

## **An Investigative Review into the Process of Establishing, Managing and Supporting Independent Reviews in Scotland**

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# An Investigative Review into the process of establishing, managing and supporting Independent Reviews in Scotland



Chaired by  
**Alison Britton, Professor of Healthcare and Medical Law, Glasgow  
Caledonian University**

# Foreword



This report is about the planning, process and execution of non-statutory reviews. Although our remit was to investigate the Scottish Independent Review of Transvaginal Mesh Implants, our recommendations are generic, systematic and may be applied to reviews more broadly.

This Review has identified a series of failures in how the Scottish Independent Review of Transvaginal Mesh Implants was conducted.

Reflecting on the failures and limitations of this process, I recognise that everyone involved in the Transvaginal Mesh Review entered into the process with the best of intentions. Conducting this Review, I met a series of civic-minded people, trying to do the right thing in difficult circumstances.

It has been my privilege to chair this Investigative Review. I appreciate the time everyone involved in this process has taken to share their perspectives, insights and experiences with us. Participating in public reviews – whether as a chair, panel member or special interest representative - can be a hard, and sometimes thankless, task.

It is important to be honest about our past failures. But it is equally important to learn lessons from the past and to shape the future in light of those lessons.

Alison Britton, Professor of Healthcare and Medical Law, Glasgow Caledonian University. 25<sup>TH</sup> October 2018

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## Executive Summary

A petition on polypropylene mesh medical devices was lodged in April 2014 to the Public Petitions Committee of the Scottish Parliament by Elaine Holmes and Olive McIlroy on behalf of the Scottish Mesh Survivors ‘Hear Our Voice’ campaign.

The Petition was lodged to draw attention to a number of women who had experienced serious complications following procedures to treat pelvic organ prolapse and stress urinary incontinence. This was linked with under-reporting of adverse events and a poor understanding as to why these complications had occurred. It received in excess of 1,700 signatures and 212 comments.

Following further evidence provided by the petitioners, Elaine Holmes and Olive McIlroy, on 17 June 2014, Alex Neil – then the Cabinet Secretary for Health and Wellbeing – informed the Committee that he intended to commission an Independent Review. The Review would not only explore the evidence that the petitioners had provided, but also consider complication rates and under-reporting of adverse events as well as looking at the overall evidence base for mesh devices.

The Scottish Independent Review Group held its first meeting on 25 August 2014.

On 27 March 2017, the Scottish Government published the Mesh Review’s Final Report, entitled *The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women*.<sup>1</sup> This was preceded by an Interim Report which was published on 2 October 2015.

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<sup>1</sup> The Scottish Government (2017) The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Final Report. Available from: <http://www.gov.scot/Resource/0051/00515856.pdf>.

Prior to the publication of the Final Report, the first chair resigned and a second chair was appointed. Three further members of the Mesh Review Group resigned. The publication of the Final Report generated widespread criticism. Concerns ranged from the evaluation and exclusion of certain evidence, to the independence of the review process, and in particular to the inclusion of the petitioners' input to the Final Report, despite their resignation and request for their contribution to be removed.

In response to these concerns, on 18 May 2017, the then Cabinet Secretary for Health and Sport, Shona Robison, advised the Public Petitions Committee of the Scottish Parliament that the process by which the Mesh Review Group came to its conclusions would in itself, be examined. An Investigative Review would be commissioned to undertake this task.

This report presents the findings of that Investigative Review. The task of this investigation has not been to reconsider the merits of the Mesh Review's substantive conclusions on the safety and efficacy of transvaginal mesh implants, nor have we sought to apportion individual blame for any failing or omissions. That was not our remit. We have however, attempted to discover what caused the Mesh Review to be received in the way that it was.

Our Report comprises 10 chapters. It takes a chronological approach, from the commissioning of the Mesh Review until its publication. The balance of this chapter introduces key information about the composition of this Investigative Review Group and our methodology. Each subsequent chapter discusses key areas in which we have identified failures or mistakes as well as lessons which can usefully be learned from the Mesh Review for the establishment, management and support of future independent reviews.

**Chapter 2** considers the importance of clarity and shared understandings in formulating the title, remit and terms of reference of any review and finds that the Mesh Review

lacked many of these essential characteristics. This lack of clarity about the aims, object and purpose of the Mesh Review, continued to follow the review process through the long and increasingly dysfunctional months of its operation.

**Chapter 3** examines the issues of independence, and conflicts and declarations of interest in the independent Review process. We identify a series of inadequacies in the approach adopted by, and record-keeping of, the Mesh Review. **Chapter 4** considers the selection and responsibilities of the Chair, while **Chapter 5** looks at important considerations in the selection and composition of members of a review.

**Chapter 6** examines the role and responsibilities of the chair and members in an independent review. **Chapter 7** considers the management and evaluation of the evidence in the course of the Mesh Review process.

**Chapter 8** focuses on the composition and production of a review report, highlighting a number of limitations in the Mesh Review's approach. **Chapter 9** considers the timeframe, administration and budget of a review, and the problems characterising the Mesh Review on all three elements.

**Chapter 10** considers the management of external influences on independent Review processes, and the impact which the publication and subsequent public and media scrutiny had on many of its members.

Having reviewed the evidence, we have concluded that the Mesh Review and the process leading up to the publication of its Final Report were characterised by systematic failures. We found that the Mesh Review was ill-conceived, thoughtlessly structured and poorly executed. Negative factors including irreconcilable differences of opinion of Review members, lack of agreement on the interpretation of evidence, unhelpful political and media influences and pressure to complete the report only served to magnify the failures in the process.



Whether the Mesh Review was independent was a recurring concern. The independence of any investigation is the spine which gives it credibility and legitimacy. Our investigation identified a number of problems with how the Mesh review solicited, monitored and reported relevant declarations and conflicts of interests by members of the Review Group.

We record a number of criticisms on how the Mesh Review was conducted. Some of these criticisms have informed our recommendations. However, we were satisfied that no one involved in the Mesh Review was acting in bad faith. On the contrary, public citizenship and sense of duty were the main factors in volunteering to be part of the Mesh Review. The same can be said of those who contributed and supported the process as Scottish Government officials.

The nature of any review, often commissioned by the Minister, whose departments have responsibility for the subject matter in question, usually arise from unanswered questions, controversy or public interest and can vary in terms of gravity and urgency.<sup>2</sup> The fact that the review should be answerable to these elements gives rise to recurring concerns which usually involve the competence of the Chair, the independence of its members, the scope of its terms of reference, and its timescales and budget.<sup>3</sup>

Although the use of independent reviews as an instrument of public policy is not without its critics,<sup>4</sup> they appear to be here to stay.<sup>5</sup> To give us an indication on the nature and

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<sup>2</sup> Howe G (1999) The Management of Public Inquiries. *The Political Quarterly* pp 294- 304 at p 295.

<sup>3</sup> See for example the summary of House of Commons Briefing Paper, Statutory Commissions of Inquiry: The Inquiries Act 2005.

<sup>4</sup> Hill A (2010) Sohan report author says public inquiries are not worth the money. *The Guardian* Available from: <https://www.theguardian.com/society/2010/sep/15/public-inquiries-ignored-lord-bichard> & Bolby C (2017) Grenfell: Can public inquiries ever satisfy everyone? *BBC News* Available from: <https://www.bbc.co.uk/news/uk-40950945> [Accessed September 5 2018].

<sup>5</sup> Norris E & Shephard M (2017) Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.6; Levitt R & Solesbury W (2012) Policy tsars: here to stay but more transparency needed. Final report. Kings College, London at p.2 Available from:



frequency of reviews commissioned in Scotland, we asked the Scottish Government to provide data on how many reviews had been commissioned over the last 5 years. We were surprised to discover that this data is not available and we recommend that such data is collected.

There are no established procedures for guidance on how to establish, progress and publish outputs of a commissioned review. Guidance tends to be piecemeal, often relying on goodwill from those who may have had some previous involvement in the review process or whoever happens to have some time to spare. We recommend that a dedicated unit be established which would bring together experience and expertise that can be drawn upon when a review or other investigation is commissioned.

Finally, it is difficult for us to adequately describe the spectrum of emotions that we encountered from those that we met. The majority of members expressed strong, negative reactions towards their involvement in the Mesh Review. This was a combination of factors revolving around interpersonal conflicts within the group, politicisation of the review process, and treatment by the media. They felt totally unprepared for the levels of public and political scrutiny that they received. Some felt traumatized in the aftermath of the publication of the Final Report. One member noted:

*“It was terrible, terrible, terrible.”*

We hope that this Report and its recommendations are seen as a useful contribution which may reduce the risk of repeating the mistakes and failures which characterised the Scottish Mesh Review process.

## Recommendations

### Chapter 1: Background and Process

- 1. We recommend that appropriate data on the frequency and nature of ‘Commissioning Inquiries, Reviews and Panels’ is collected, recorded and reported. This will help provide an understanding of the review process more generally and inform best practice for future reviews.**
- 2. We recommend that a distinction is made between those which have been established within a statutory framework and those which have not. Including this detail on a website will inform the public understanding.**
- 3. We recommend that there would be merit in setting up a dedicated unit to support commissioned reviews. This unit could provide a common knowledge base for both non-statutory and statutory reviews. It could keep records of previous reviews and collate data on their conclusions and outputs. It could provide guidance and templates for establishment of a review and for scoping terms of reference. These documents could be updated to reflect best practice and experience.**

## **Chapter 2: The title, remit and terms of reference of a review.**

- 4. We recommend that, where possible, the chair is involved in the decision of what the title of the review should be.**
- 5. We recommend that material or key terms contained in a title should be explicitly defined and agreed by members.**
- 6. We recommend that, if possible, the chair should be the principal author in the drafting of the remit.**
- 7. We recommend that the interests and expertise of all members are considered when drafting and agreeing the remit.**
- 8. We recommend that the rationale for the remit is clearly agreed.**
- 9. We recommend that consideration should be given as to who sets the terms of reference. For example, this could be the chair or the commissioning Minister or a combination of both.**
- 10. We recommend that all members of a review should have the opportunity to contribute to the development of the terms of reference.**
- 11. We recommend that the Government consider providing a guide and template to drafting terms of reference. It should be generic in nature to meet the diversity of investigations.**
- 12. We recommend that a period be set aside to consult on the terms of reference. This would enhance legitimacy, promote transparency, confidence and trust in the review process. We recognize that this must be offset against other possible limitations, for example, constraints on time.**

### **Chapter 3: Independence and conflicts of interest/declarations of interest.**

- 13. We recommend that the chair identifies areas that may have the potential to compromise the independence of the investigation. This is part of his or her overall duty to ensure an effective inquiry process and public confidence in the outcomes and recommendations.**
- 14. We recommend applying a test of 'impartiality'. This would allow someone with prior knowledge or involvement in the subject matter to be a potential member on the basis that their involvement was disclosed and evaluated.**
- 15. We recommend that a process should be in place to identify and measure potential conflicts of interest to ensure that a proportionate response can be made.**
- 16. We recommend that the chair has responsibility to lead the members of the review in discussion to consider possible conflicts of interest.**
- 17. We recommend that the importance of transparency and accountability in the completion of Declaration of Interest should be explained as part of a general induction process.**

#### **Chapter 4: The selection/ appointment and responsibility of the chair.**

- 18. We recommend that the appointment process to select the chair should be open and transparent.**
- 19. We recommend that the commissioning party should ensure that the chair possesses skills specific to the nature of the inquiry. The commissioning party should also have a continuing responsibility to ensure that the chair promotes accountability and confidence in the inquiry process.**
- 20. We recommend that support and some sort of induction, including background materials be given prior to undertaking the role. The former is especially important if the prospective chair is undertaking the role for the first time.**
- 21. We recommend that a system of mentorships be established and a pool of those who have had experience chairing a Government review be available to draw upon to support a novice chair.**
- 22. We recommend that potential appointees have no perceived conflict of interest which may raise doubts on impartiality and independence.**
- 23. We recommend that the chair should be involved in the selection process of potential review members.**

### **Chapter 5: Selection and composition of members of a review**

- 24. We recommend that guidelines should be developed detailing the procedure which is required to establish an independent review. These guidelines should be in a form which can be modified and standardised over time. We believe that the more widely used they become, the more accepted they become.**
- 25. We recommend that the process for the selection of members should be as independent of the subject or area under review, as possible.**
- 26. We recommend that criteria should exist to determine the composition and balance of review members in relation to the subject matter under review.**
- 27. We recommend that the chair should be the first appointment and that members should be either selected by the chair or in consultation or approved by the chair.**
- 28. We recommend that the degree of external control of a review may also have to be considered within the – sometimes competing – interests of constraints on time and costs. The process for evaluation and selection should be transparent and accountable and if possible, undertaken by someone outwith the area or subject being reviewed**
- 29. We recommend that an evaluation of the merits of having special interest representation in a review should be guided by the nature and requirements of the review.**
- 30. We recommend that alternative approaches be considered in whether it is more appropriate to have this representation as part of a sub group with an effective spokesperson to feedback discussion to the core group.**

#### **Chapter 6: Role and conduct of the chair and members of a review.**

- 31. We recommend that a process be established to manage any changes to the membership of a review. The process should include matters such as intimation of any resignations and consideration of replacements and quoracy.**
- 32. We recommend that a review should agree, at the outset, what it is seeking to establish and the methodology of how this can be achieved. Whilst we would anticipate that an investigative/inquisitorial approach may be the norm<sup>1</sup> it would depend on the nature and requirements of the review.**
- 33. We recommend that group members of a review have equal access to information and points of contact.**
- 34. We recommend that consideration be given to providing members of a review with appropriate training and induction covering matters such as conduct and responsibilities, as well as matters pertaining to confidentiality, information sharing outwith the group and how to manage enquiries from the media.**

#### **Chapter 7: Management and evaluation of the evidence.**

- 35. We recommend that a methodology to evaluate evidence should be understood and agreed by all members of a review.**



**Chapter 8: The composition and production of a review report.**

- 36. We recommend that it is clearly defined who has editorial control for the structure and composition of any report.**
- 37. We recommend that there is a clear understanding of who has responsibility for the printing and publication of any report.**

### **Chapter 9: The timeframe, administration and budget of a review.**

- 38. We recommend that there should be a clear and realistic indication of the timeline of a review. This should be included in the terms of reference.**
- 39. We recommend that the commissioning party should provide oversight and support to the chair to manage and review any lapse in timescale.**
- 40. We recommend that consideration should be given to the creation of a dedicated administrative support unit within the Scottish Government. This unit could be utilised for all commissioned reviews.**
- 41. We recommend that the ultimate responsibility for the content of the minutes rests with the chair.**
- 42. We recommend that there should be a template that standardises what is presented at the conclusion of a Review, and how this information is presented.**
- 43. We recommend that a budget should be identified at the beginning of any discussion on the commission of a review.**
- 44. We recommend that the chair and members should be advised if there is to be remuneration for membership and, if so, agreement should be reached on the terms of any remuneration.**

**Chapter 10: The management of external influences.**

- 45. We recommend that if there is reason to believe that the subject under review will attract media and wider public interest, there should be support and media training for both the chair and members of the review.**
- 46. We recommend that training should be provided and reassurances given to members that advice and support to manage media scrutiny is available.**

## Chapter 1: Background and Process

1. A petition on polypropylene mesh medical devices was lodged in April 2014 to the Public Petitions Committee of the Scottish Parliament by **Elaine Holmes** and **Olive McIlroy** on behalf of the Scottish Mesh Survivors “**Hear Our Voice**” campaign.<sup>6</sup> The petition called on the Scottish Parliament to urge the Scottish Government to:

1. Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;
2. Initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world;
3. Introduce mandatory reporting of all adverse incidents by health professionals;
4. Set up a Scottish Transvaginal Mesh implant register with a view to linking this up with national and international registers;
5. Introduce fully Informed Consent with uniformity throughout Scotland’s Health Boards; and
6. Write to the MHRA [The Medicines and Healthcare Products Regulatory Agency] and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.<sup>7</sup>

2. The Petition was lodged to draw attention to a number of women who had experienced serious complications following procedures to treat pelvic organ prolapse and stress urinary incontinence. This was linked with under-reporting of adverse events and a poor understanding as to why these complications had occurred.<sup>8</sup> It received in excess of 1,700 signatures and 212 comments.<sup>9</sup>

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<sup>6</sup> PE1517.

<sup>7</sup> PE 1517 was lodged on 30<sup>th</sup> April 2014. For a full chronology, see <http://www.parliament.scot/GettingInvolved/Petitions/scottishmeshsurvivors>.

<sup>8</sup> See the preface of both The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women Interim Report.

3. On 3 June 2014,<sup>10</sup> the Public Petitions Committee took evidence from Olive Holmes and Elaine McIlroy (hereafter referred to as '**the petitioners**') who provided more detail on what had led them to lodge the petition.
4. On June 17 2014, **Alex Neil**, then the Cabinet Secretary for Health and Wellbeing, informed the Committee that he intended to commission an Independent Review.<sup>11</sup> The Review would not only explore the evidence that the petitioners had provided, but also consider complication rates and under-reporting of adverse events.<sup>12</sup>
5. The Scottish Independent Review Group (hereafter referred to as the '**Mesh Review Group**') held its first meeting on 25 August 2014.
6. On 27 March 2017, the Scottish Government published the Mesh Review's Final Report entitled, *The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women*.<sup>13</sup> This was preceded by an Interim Report which was published on 2 October 2015.<sup>14</sup>
7. Prior to the publication of the Final Report, the first chair, **Dr Lesley Wilkie**, resigned and a second chair, **Dr Tracey Gillies**, was appointed. Three further members

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(2015) Available from: <https://www.gov.scot/Resource/0048/00486661.pdf>. The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women Final Report. (2015) at Available from: <https://www.gov.scot/Resource/0051/00515856.pdf> [Accessed September 12 2018].

<sup>9</sup> Official Report. Meeting of the Parliament. Dec 5 2017 col. 28.

<sup>10</sup> Public Petitions Committee (session 4) Official Report 3 June 2014.

<sup>11</sup> Public Petitions Committee (Session 4), Official Report, 17 June 2014, col 2364.

<sup>12</sup> Public Petitions Committee (Session 4), Official Report, 17 June 2014, col 2364.

<sup>13</sup> The Scottish Government (2017) *The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Final Report*. Available from: <http://www.gov.scot/Resource/0051/00515856.pdf>. Hereafter, the "Final Mesh Report."

<sup>14</sup> The Scottish Government (2015) *The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Interim Report*. Available from: <http://www.gov.scot/Resource/0048/00486661.pdf>. Hereafter, the "Interim Mesh Report."

of the Mesh Review Group resigned, including the petitioners. The third resignation was a clinician member, **Dr Wael Agur**.

8. The publication of the Final Report generated widespread criticism over a range of concerns including the evaluation and exclusion of certain evidence, the nature and quality of the independence of the review process, and the inclusion of the petitioners' input despite their resignation and request for their contribution to be removed.

### Membership and Remit of our Investigative Review Group

9. In response to the concerns raised, on 18 May 2017, the then Cabinet Secretary for Health and Sport, **Shona Robison**, advised the Public Petitions Committee of the Scottish Parliament that the process by which the Mesh Review Group came to its conclusions would be examined.<sup>15</sup> An Investigative Review would be commissioned to undertake this task. Professor Alison Britton was asked to lead the new Investigative Review.

10. The Membership of our Investigative Review Group was:

- Alison Britton - Professor of Healthcare & Medical Law, Glasgow School for Business and Society, Glasgow Caledonian University;
- Gerard Sinclair – Chief Executive and Principal Solicitor of the Scottish Criminal Cases Review Commission;
- Dr Ealasaid Munro – Senior Lecturer in Media and Communication, University of Stirling;

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<sup>15</sup> Cabinet Secretary for Health and Sport submission of 17 May 2017 Available from: [http://www.parliament.scot/S5\\_PublicPetitionsCommittee/Submissions%202017/PE1517\\_LL\\_CabSec\\_170517.pdf](http://www.parliament.scot/S5_PublicPetitionsCommittee/Submissions%202017/PE1517_LL_CabSec_170517.pdf) [Accessed June 27 2018].

- Research – Yousaf Kanan, Fast Stream Research Officer, Health and Social Care. Scottish Government;
- Administration – Irene Brown, Administrator, Directorate of School Professional Services, Glasgow Caledonian University;
- Transcription - Alison Lockhart, Research Advisor, Glasgow Caledonian University.

11. Each member sat in a personal capacity and did not represent the views of any organisation or body.

12. The remit of our Investigative Review was:

“To consider the evidence on how to improve the investigative review process. Specific reference will be made to the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women.<sup>16</sup> This will inform recommendations for the process of establishing, managing and supporting Independent Reviews in Scotland.”

### Structure of this Report

13. This Report presents our findings. Our Report comprises 10 chapters. It takes a chronological approach, from the commissioning of the Mesh Review until its publication. The balance of this chapter introduces key information about the composition of this Investigative Review Group and our methodology. Each subsequent chapter discusses key areas in which we have identified failures or, mistakes as well as lessons which can usefully be learned from the Mesh Review for the establishment, management and support of future independent reviews.

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<sup>16</sup> But not limited to.



14. **Chapter 2** considers the importance of clarity and shared understandings in formulating the title, remit and terms of reference of any review and finds that the Mesh Review lacked many of these essential characteristics. This lack of clarity about the aims, object and purpose of the Mesh Review, continued to follow the review process through the long and increasingly dysfunctional months of its operation.

15. **Chapter 3** examines the issues of independence, and conflicts and declarations of interest in the independent Review process. We identify a series of inadequacies in the approach adopted by, and record-keeping of, the Mesh Review. **Chapter 4** considers the selection and responsibilities of the Chair, while **Chapter 5** looks at important considerations in the selection and composition of members of a review.

16. **Chapter 6** examines the role and responsibilities of the chair and members in an independent review. **Chapter 7** considers the management and evaluation of the evidence in the course of the Mesh Review process.

17. **Chapter 8** focuses on the composition and production of a review report, highlighting a number of limitations in the Mesh Review's approach. **Chapter 9** considers the timeframe, administration and budget of a review, and the problems characterising the Mesh Review on all three elements.

18. Finally, **Chapter 10** considers the management of external influences on independent Review processes, and the impact which the publication and subsequent public and media scrutiny had on many of its members.

### Intended Audience

19. Although our report was commissioned by the office of the Cabinet Secretary for Health and Sport, we anticipate that it will have a wide and diverse reading audience. It has therefore been written with that diversity of interests in mind. Where technical terms have to be used, an explanation or links to further explanation can be found in the

endnotes. If we have made reference to other literature, a reference to this can also be found in the endnotes.

## Legal Context

20. The focus of our investigation is a non-statutory, *ad hoc*<sup>17</sup> review as opposed to a statutory inquiry which has been established under the Inquiries Act 2005. There is, however, a wealth of information which has been written in relation to the latter and we have drawn freely upon that literature. Both forms share certain core principles – subject to some differences in form and procedure<sup>18</sup> – which raise common themes and pose similar questions.<sup>19</sup> Reviews are commissioned for a wide variety of reasons. Generally, they aim to provide a public account on what has occurred and why it has occurred. A successful review aims to restore public confidence and provide reflection and lessons to reduce the likelihood of the event or circumstances occurring again in the future.<sup>20</sup>

21. The nature of the commission and the remit and terms of reference means that each review will have its own unique characteristics and requirements,<sup>21</sup> and a rigid set

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<sup>17</sup> *ad hoc*- ‘created or done for a particular purpose as necessary.’

<sup>18</sup> Sulitzeanyu-Kenan R (2006) “If they get it right: An experimental test of the effects of the effects of the appointment and reports of UK public inquiries” *Public Administration* Vol. 84, No. 3, 2006 623–653 at 625.

<sup>18</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from:  
<http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf>  
[Accessed November 7 2017] at p.9.

<sup>19</sup> Sulitzeanyu-Kenan R (2006) “If they get it right: An experimental test of the effects of the effects of the appointment and reports of UK public inquiries” *Public Administration* Vol. 84, No. 3, 2006 623–653 at 625.

<sup>19</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from:  
<http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf>  
[Accessed November 7 2017] at p.10.

<sup>20</sup> Sulitzeanyu-Kenan R (2006) “If they get it right: An experimental test of the effects of the effects of the appointment and reports of UK public inquiries” *Public Administration* Vol. 84, No. 3, 2006 623–653 at 625.

<sup>21</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from:

of processes may not suit all reviews. There is no presumption that a statutory inquiry will be commissioned in preference to its non-statutory *ad hoc* counterpart.<sup>22</sup> Each has its own purpose and place.

22. There are three main distinctions to be made between a statutory inquiry and a non- statutory review. The latter will usually be conducted in private. Those who are called to give evidence are not required to do so under oath. Non-statutory investigations cannot compel attendance of any witnesses.

23. Under section 28 of the Inquiries Act 2005, the Scottish Government has the power to commission a public inquiry but only where the matter concerned is devolved.<sup>23</sup> Transvaginal mesh products are classed as medical devices whose regulation is a matter reserved to the United Kingdom Parliament.<sup>24</sup>

## Evidence gathering process

24. In carrying out our remit, we first read the Interim and Final Reports of the Mesh Review Group to gain an initial understanding and context of the Review. Once this was complete, our main focus was to speak with those who were directly involved as members of the Review. We contacted everyone who appeared on the membership list

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<http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] at p.9.

<sup>22</sup> Further discussion on this point can be found in Caird J S House of Commons Library (2016) Public Inquiries: non-statutory commissions of inquiry. Briefing paper no. 02599. Available from:

<http://researchbriefings.parliament.uk/ResearchBriefing/Summary/SN02599#fullreport> [Accessed August 12 2018]

<sup>23</sup> Further discussion can be found in Scottish Government (2014) SPICe Briefing for the Public Petitions Committee. Available from:

<http://www.parliament.scot/ResearchBriefingsAndFactsheets/Petitions%20briefings%20S4/PB14-1517.pdf>

[Accessed September 4 2018].

<sup>24</sup> Scotland Act 1998, Schedule 5, Section J4.

contained in the Final Report of the Mesh Review, inviting them to meet with us.<sup>25</sup> 17 out of 24 members listed in the Final Report met with us or submitted written evidence.

25. A short, Plain Language Statement, containing our terms of reference and remit was made available to those with whom we wished to meet. Meetings were recorded and transcribed. All interviewees had the opportunity to review their own transcripts. The transcripts were then read by us and themes identified. Occasionally, interviewees provided additional information which had not been part of the original discussion. We have recognised these as additions which informed our work, but they have not been included in the thematic review of the transcripts. Where it was not possible to meet with members of the Mesh Review in person, we spoke on the telephone.

26. We also received a joint written submission from the petitioners. This was treated in the same way as the transcripts arising from the 'face to face' discussions that we had with members of the Mesh Review. We included what we considered to be pertinent sections of their submission in our Report. The evaluation of what was a pertinent section was based upon the questions that we asked those with whom we met. The petitioners' written submission can be found in Annex 2 of this document.

27. A call for evidence was made and a Focus Group was held. The Focus Group comprised of representatives from academia, law and public policy as well as a previous chair of a Scottish Independent Review. The Focus Group was invited to discuss themes that had arisen from our interviews. We also considered some of the more general issues that had arisen as the Mesh Review progressed. The outcome of our discussions helped us as a Group to shape our thinking and test our conclusions. The Focus Group made a significant contribution to our recommendations.

28. We met with the Convener and Deputy Convener of the Public Petitions Committee of the Scottish Parliament. We also met with **Alex Neil** MSP, as former

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<sup>25</sup> The Scottish Government (2017) Final Mesh Report at p. 102.

Cabinet Secretary for Health and Wellbeing and with **Jackson Carlaw** MSP and **Neil Findlay** MSP.

29. We considered literature which touched upon issues of relevance to our remit and we have been able to draw upon their content during our deliberations.<sup>26</sup>

30. One of our initial tasks was to ascertain the frequency and type of investigations that are commissioned and conducted in Scotland. We asked the Scottish Government to provide data on how many reviews had been commissioned over the last 5 years and the subject of their investigation. This data is not available. It is complicated by the fact that reviews are called different things. The area of the Scottish Government's website which details "Commissioning Inquiries, Reviews and Panels" provides a list of investigations which are current and those which have been closed and archived.<sup>27</sup> Whilst some may include the words 'commission' 'review' or 'panel', others do not and there are no definitions on what these are nor how, they ought to, or if they should be, distinguished.

**We recommend that appropriate data on the frequency and nature of 'Commissioning Inquiries, Reviews and Panels' is collected, recorded and reported. This will help provide an understanding of the review process more generally and inform best practice for future reviews.**

**We recommend that a distinction is made between those which have been established within a statutory framework and those which have not. Including this detail on a website will inform the public understanding**

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<sup>26</sup> This included the (2015) Interim and (2017) Final Mesh Reports. We also considered the Report published in July 2017 by the Mesh Oversight Group, chaired by Professor Keith Willett- Mesh Oversight Group Report. Available from: <https://www.england.nhs.uk/wp-content/uploads/2017/07/mesh-oversight-group-report.pdf>. This Report follows on from the Mesh Working Group Interim Report of December 2015. Available from: <https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf>.

<sup>27</sup> Scottish Government. Commissions, Inquiries, Reviews and Panels. Available from: <https://www.gov.scot/About/Review> [Accessed August 10 2018].

31. We considered evidence given to the Public Petitions Committee of the Scottish Parliament and parliamentary questions and debate. We recognize that the majority of that evidence was submitted after the publication of the Final Report of the Mesh Review; however we believe it would have been an omission on our part not to consider those questions and the evidence that was presented.

32. Those who participated as members of the Mesh Review often expressed strong views in our meetings with them and we wanted to reflect that in our Report. We have therefore included quotations and, where possible, have anonymised these. All quotations appear in *italics*. We took a thematic approach to the questions posed which were shaped by the interests, experience and professional representation of the members of the Mesh Review.

33. Finally, throughout our work, we were struck by the fact that there are no established procedures or guidance on how to establish, progress and publish outputs of a commissioned review. Guidance tends to be piecemeal, relying on goodwill from those who may have had some previous involvement or whoever happens to have some time to spare. Detailed guidance on running reviews would also have value for investigations more generally since statutory inquiries similarly have no such guidance. The call for such guidance and some way to pull, currently disparate, strands of knowledge together has been enduring<sup>28</sup> and broad.<sup>29</sup>

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<sup>28</sup> Howe G (1999) The Management of Public Inquiries. *The Political Quarterly Publishing Co. Ltd* pp 294- 304 at p 295.

<sup>29</sup> Norris E & Shephard M (2017) Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.5. See also the summary of House of Commons Briefing Paper, Statutory Commissions of Inquiry: The *Inquiries Act 2005*. at p. 6. See also, The Economist (2016) Question Time. Public Inquiries Available from: <https://www.economist.com/britain/2016/10/20/question-time> [Accessed September 20 2018].

34. A dedicated centre for public investigation<sup>30</sup> would bring together experience and expertise that can be drawn upon when a review or other investigation is being commissioned. It could provide a common knowledge base and be a repository for best practice. It could advise on the most effective way to ensure appropriate administrative support and IT equipment.<sup>31</sup> It could provide guidance on how to appoint and recruit members of a review. It could provide templates to assist with the title and remit of a review; these could also be used to help scope and draft terms of reference. It could introduce novice chairs and members to those who have previous experience and would be willing act as mentors. It could provide guidance for members on how to cope with intense public and media scrutiny. It could also provide a mechanism for a review to share methodologies, conclusions and recommendations<sup>32</sup>. Looking forward, it could monitor the implementation of the recommendations arising from a concluded review.

**We recommend that there would be merit in setting up a dedicated unit to support commissioned reviews. This unit could provide a common knowledge base for both non- statutory and statutory reviews. It could keep records of previous reviews and collate data on their conclusions and outputs. It could provide guidance and templates for establishment of a review and for scoping terms of reference. These documents could be updated to reflect best practice and experience.**

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<sup>30</sup> There is a rich variety of literature which may refer to this proposal using slightly different names but they all capture the themes suggested here and many more.

<sup>31</sup> For a good summary of these suggestions and more, please see Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective Inquiries - Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] at p. 20 – 21.

<sup>32</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from: [https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p. 72 [Accessed June 29 2018].



35. We would like to thank all the individuals who contributed to our work by sharing their thoughts, experience and knowledge. For some, this was a difficult and emotional experience. A list of those individuals with whom we met or received evidence is set out at Annex 1.

## Chapter 2: The title, remit and terms of reference of a review

### The title

36. The title of a review should provide an immediate and accurate indication of the subject matter under investigation.

37. Some reviews have a short title, for example, *The Commission on Women Offenders*.<sup>33</sup> Others are more specific, and refer to their published documentation, for example, *The Independent Review of Hate Crime Legislation in Scotland: Final Report*.<sup>34</sup>

38. The title will usually be directed by the nature of what is to be reviewed and provided by the person who has commissioned it. If a chair has already been appointed, this may have been done in consultation with them. The terms within the title should describe the key elements of what will be considered. These key or material elements should be commonly understood by all members of the review. Finally, the title should set the tone of the review.

### The Mesh Review

39. The Mesh Review was entitled: *The Scottish independent review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women*. The first chair confirmed that the title

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<sup>33</sup> Commission on Women Offenders was chaired by the Right Hon Dame Elish Angioli. Available from: <https://www.gov.scot/Topics/archive/reviews/commissiononwomenoffenders/finalreport-2012> [Accessed June 27 2018].

<sup>34</sup> Independent Review of Hate Crime Legislation in Scotland: Final Report was chaired by Lord Bracadale. Available from: <https://www.gov.scot/Publications/2018/05/2988> [Accessed June 27 2018].

had already been decided and given to her by Scottish Government officials. Key words in this title included “Scottish”, “independent”, “safety” and “efficacy.”

40. We asked members if they recalled whether the terms “safety” and “efficacy” were initially included and if their meanings were defined and agreed. There was a lack of consensus regarding whether safety and efficacy were part of the original title. Some believed it was, but the majority said that it came about as a result of the first meeting, although its inclusion was not contentious. One petitioner’s testimony to the Public Petitions Committee recalled this differently saying that she had to “fight” to get the word “safety” into the title of the review.<sup>35</sup>

41. As to how these critical words were defined: *“I don’t think those were defined as to the way in which they were to be used.”* Others agreed adding, *“not to my recollection.”* Some members had a clear definition of what safety and efficacy meant to them; whereas for others the definitions were less clear: *“safety I think is slightly easier, but efficacy I think is a very difficult one.”* One member believed that the clinicians and petitioners members were *“focusing on different things”* when they were using these terms. Another acknowledged that “safety” may not always be the same as “benefit” noting that the *“final arbiters of benefit are between a patient, the clinician and the informed consent process.”*

42. The majority of the Review members did not recall the definitions of safety and efficacy being discussed. There was some suggestion that a common understanding was reached, however this was not supported by the divergence of response from members, or the supporting evidence provided from the Group meetings.

43. A lack of definition and agreement as to how these terms should be understood caused many challenges as the review progressed. As one member observed:

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<sup>35</sup> Official Report. Meeting of the Parliament. Dec 5 2017 col. 29.

*“When you don’t have a common outcome measure in terms of the research and publications, you then end up with this question which comes up halfway during the Review, what does efficacy mean?”*

**We recommend that, where possible, a chair is involved in the decision of what the title of the review should be.**

**We recommend that material or key terms contained in a title should be explicitly defined and agreed by members.**

### **The remit**

44. The remit involves the areas of activity that the review will undertake to meet the terms of reference. It should sit consistently with, and expand upon, the key words contained in the title.<sup>36</sup>

45. Given that the chair has the responsibility to lead and ensure that a review fulfils its remit, where possible, he or she should be involved in drafting it. We recognize that this may depend on the nature of the investigation. Whatever approach is adopted, the rationale for the remit should be clear. A process should be in place so that the chair and the members of the review are aware of the remit and agree to work towards its fulfilment.

### **The Mesh Review**

46. The remit of the Mesh Review was:

To evaluate both the efficacy and extent of the causes of adverse incidents and complications associated with transvaginal mesh surgery for Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP).<sup>37</sup>

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<sup>36</sup> Consider the above example of the Independent Review of Hate Crime Legislation in Scotland: Final Report. In the remit the concepts of hate crime and the judicial process were expounded and explained. Available from: <https://www.gov.scot/Publications/2018/05/2988> [Accessed June 27 2018].

47. How the remit for the Mesh Review was decided or agreed upon remains unclear. *“I don’t know. I wasn’t involved so whoever drew it up, I’ve no idea.” “We were very much given a remit.” “I don’t remember the remit being set by us.”*

48. There were different recollections as to where the remit originated, with some suggestions that a *“rough guide”* was provided by Scottish Government officials; no one was clear. No one described making any attempt to change or amend the remit.

### Was the remit achievable?

49. The majority of Review members believed it to be achievable but only if it was understood against what may be construed as narrower, clinical definitions. If this was opened up to include and represent the broader interests of the whole membership of the Review, then achieving the remit appeared more doubtful.

50. Probably *“depended on what you wanted to achieve.”*

*“the remit was: ‘is there a place for these clinical procedures?’”*

*“If the remit was – ‘should we ban the tapes?’ – that was slightly different.”*

51. Some, including the second chair, regarded the Mesh Review primarily as a clinical review. If that were so, she should have had influence over the direction and conclusions that would flow from that interpretation.

52. Given the wider representation of interests on the Review Group, it would be unsurprising if others expected it to consider more than just clinical guidance. Consideration should also have been given not just to the membership of the Review but also who were the intended audience? There were diverse and competing interests represented by the membership of the Mesh Review. Although this would not be unusual in the composition of any review, there seems to have been no opportunity

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<sup>37</sup> The Scottish Government (2017) Final Report at p. 9, section 1.2.

to agree on how membership and public interests would be represented within the remit. If the remit was simply to be viewed from a clinical perspective, then perhaps the approach could have been agreed. However, given there were 26 members, many of whose interests and expertise were not clinical, this needed to be acknowledged.

53. Insufficient consideration was given to discussing and agreeing the remit. Given this lack of resolution toward a common understanding and approach, it is understandable that the remit was never going to achieve its stated aims.

**We recommend that, if possible, the chair should be the principal author in the drafting of the remit.**

**We recommend that the interests and expertise of all members are considered when drafting and agreeing the remit.**

**We recommend that the rationale for the remit is clearly agreed.**

## **The Terms of Reference**

54. The terms of reference defines the purpose and structure of a review.<sup>38</sup> It also provides the chair with the authority to carry out its remit.<sup>39</sup> Getting the scope and content of the terms of reference right is critical to a successful outcome. Conversely, vague and confused terms of reference will result in vague and confused investigations, considerations and conclusions.

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<sup>38</sup> Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p. 14.

<sup>39</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from: [https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p. 18 [Accessed June 29 2018].

55. Terms of reference can set the ground rules for process, governance, timescales, budget and outputs.<sup>40</sup> The challenge for any terms of reference is to provide sufficient focus but retain a flexibility to meet the demands of the remit. It must steer a clear, consistent and accountable path between competing or predominating interests.

56. Drafting terms of reference may be approached in different ways. Again, this will depend on the nature of the investigation. A blank sheet of paper may be welcomed by some chairs but, for most, this will be daunting. A flexible approach may allow for the commissioning party – for example, the Minister – to provide a scoping document which outlines the central issues and how they could be addressed. This can then be considered and, if necessary, amended by the chair.

57. If appropriate, it may be valuable for the chair and members to consult with stakeholders both within the review group and external to the review.<sup>41</sup> This will allow them to share any concerns and outline what they expect in terms of outcomes from the review. Having such involvement from the outset may allow expectations to be expressed, understood and interests aligned. This would need to be factored in to the proposed length of a review but the fact that such a consultation has occurred from the outset may also help build trust and confidence in the process from the outset.<sup>42</sup>

## **The Mesh Review**

58. A Transvaginal Meshes Working Group (TMWG) – often referred to as the Short Life Working Group by its members – had been in existence since 2013. The Mesh

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<sup>40</sup> House of Lords Select Committee on the Inquiries Act 2005 (2014) *The Inquiries Act 2005: Post-legislative scrutiny*, The Stationery Office, p.5.

<sup>41</sup> Centre for Effective Dispute Resolution (2015) *Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies*. Available from: [https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry - Guidance for Chairs and Commissioning Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at pp. 31-32 [Accessed June 29 2018].

<sup>42</sup> This was the approach taken in the Grenfell Tower Inquiry as discussed in the report of the Institute for Government ((2017) *How Public Inquiries can lead to change*. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.15.



Review Final Report notes that this was established at the request of Alex Neil MSP, as Cabinet Secretary.<sup>43</sup> An Expert Group evolved as development of the TMWG and held its first meeting in February 2014.

59. The TMWG was initiated “to develop a clearer understanding of the issues affecting women who had suffered complications from mesh surgery.”<sup>44</sup>

60. The Expert Group was established to “look at ways of improving clinical practice, including developing pathways of care for women experiencing complications and to improve the consent process to ensure women are better informed of the risks and benefits of all procedures available to treat these conditions.”<sup>45</sup>

61. When she received the draft Terms of Reference for the Mesh Review, the first chair believed that it had been written originally for the Short Life Working Group. A similar view was shared by another member who speculated that the draft terms of reference was “*copied over*” from the Expert Working Group. The first chair did express some concerns about the extent to which one set of terms could be applicable to a different working group with a different remit. She contributed what she described as “*minor changes*” which she believed made the Terms of Reference more applicable to the Mesh Review.

62. Incorporating an agreed definition of key terms was discussed at the first meeting of the Mesh Review. The Minutes from the meeting reflect that.<sup>46</sup>

“The Group discussed use of the word ‘safe’, agreeing that the product, location of the product, selection of patient and the procedure itself are relevant factors,

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<sup>43</sup> The Scottish Government (2017) Final Mesh Report at p.7.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> This was held on August 25 2014.

supporting the view that a definition of 'safety' must be included within the terms of reference."<sup>47</sup>

63. No agreed definition of safety was ever subsequently included in the terms of reference.

64. Given the Mesh Review had a second chair, consideration should also have been given as to whether the terms of reference could be changed at a later stage in the Review and who had the mandate to do this. The second chair was not given an option to revise the terms of reference. In hindsight she believed that she should have been more proactive in proposing some changes in an attempt to make the terms of reference more applicable to the stage that the Review had reached when she assumed the role.

65. A few members were brought into the Mesh Review Group after the remit and terms of reference had been established, so a proportion of the membership didn't have the opportunity to comment on the framework they were using.

66. A draft term of reference was circulated to the members of the Mesh Review but the extent to which this was discussed or amended varies in the members' recollection. It is probable that the draft version for the Mesh Review evolved from terms of reference that had been written for the Short Life Working Group/Expert Group. Given that some individuals were members of either one or both groups in addition to the Mesh Review, it seems likely that these terms of reference may have been conflated in their recollections or otherwise gave rise to confusion. Some members joined the group at a later stage and had no opportunity to contribute to the drafting process.

67. Neither of the chairs received guidance on what their role was in relation to the drafting or amending the terms of reference. This would have been particularly

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<sup>47</sup> Extract from the Minutes of the Independent Review, (paper no. IR/09) from meeting of August 25 2014.

confusing for the first chair who was provided with a document which had already been written, albeit for another working group. Both chairs felt, in hindsight, that they could have been more proactive in refining the terms of reference to reflect their perception of the work of the Mesh Review and their understanding of how such a review should proceed.

68. We recognise that it requires skill to be able to draft an appropriate term of reference so that focus is provided but which still allows sufficient flexibility for the investigation. That should be the proposed aim.

69. Clear and concise terms of reference are critical to the successful outcome of an independent review. Effective terms of reference provide focus and set boundaries.<sup>48</sup> It scopes out the work of the review and gives a mandate to both the chair and the members of the review to fulfil its remit. A wide range of organisations have, in the past, provided suitable guides regarding the factors which should be considered in drafting terms of reference. Some guides also include a template to aid the creation of terms of reference.<sup>49</sup>

70. Consideration should be given as to who is going to set the terms of reference. A chair may have been appointed who has not undertaken this type of work previously and requires support and guidance so he or she can contribute to the drafting process.

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<sup>48</sup> As No 1 above at pp 9-11 and Fieldfisher (2008) A practical guide to commissioning and conducting investigations and inquiries. Available from: <http://www.fieldfisher.com/publications/2008/12/a-practical-guide-to-commissioning-and-conducting-investigations-and-inquiries#sthash.3ntg9w8D.dpbs> [Accessed November 7 2017]

<sup>49</sup> See for example, The World Bank Independent Evaluation Group Communication, Strategy, and Learning International Bank for Reconstruction and Development (2011) WRITING TERMS OF REFERENCE FOR AN EVALUATION: A HOW-TO GUIDE. Available from: [http://siteresources.worldbank.org/EXT/EVACAPDEV/Resources/ecd\\_writing\\_TORs.pdf](http://siteresources.worldbank.org/EXT/EVACAPDEV/Resources/ecd_writing_TORs.pdf) or National Institute for Health Research- Involve (2017) Terms of reference template. Available from: <http://www.invo.org.uk/getting-started/template-one/> [Accessed November 7 2017].

71. There should be a provision in place to address the situation where, if a material change of circumstances arises, such as the resignation of a chair, the terms of reference can be revisited and amended accordingly.

**We recommend that consideration should be given as to who sets the terms of reference. For example, this could be the chair or the commissioning Minister or a combination of both.**

**We recommend that all members of a review should have the opportunity to contribute to the development of the terms of reference.**

**We recommend that the Government consider providing a guide and template to drafting terms of reference. It should be generic in nature to meet the diversity of investigations.**

**We recommend that a period be set aside to consult on the terms of reference. This would enhance legitimacy, promote transparency, confidence and trust in the review process. We recognize that this must be offset against other possible limitations, for example, constraints on time.<sup>50</sup>**

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<sup>50</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] atp.10.

## Chapter 3: Independence and conflicts of interest/declarations of interest

72. We have defined the term ‘independent’ as the spine which should run through any investigation. An investigation which is not perceived as independent can lead to public lack of confidence in the process and its outcomes.

73. We used ‘conflict of interest’ as the situation or experience or interest that may give rise to questions of independence.

74. Finally, we used the term ‘declaration of interest’ as the mechanism or process which facilitates exploration, examination and declaration of a possible conflict.

### What is independence?

75. Independence is an amorphous concept. It can be defined in different ways depending on what it is believed to represent. For some, independence means to be free from influence or interference such as from political, or media influences. For others it can be seen as the cornerstone of credibility or legitimacy. It may also be equated with concepts of fairness or impartiality.

76. The independent element of any review commissioned requires that the members’ opinions, findings, conclusions, judgements, and recommendations have been reached after setting personal views aside. If this has not occurred, the value of the findings of the review may be compromised or undermined.<sup>51</sup>

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<sup>51</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from:

[https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p35 [Accessed August 12 2018].

77. Organisations that have produced guidance on the principles of independence tend to distinguish two themes (a) independence of mind and (b) independence in appearance; sometimes referred to as “perceived” independence.<sup>52</sup> Appointed members not only have to be objective in their actions but must be seen to be acting objectively.

78. Demonstrating independence in an *ad hoc* review, as opposed to an inquiry established under statutory provisions, has the added hurdle that its meetings and discussions are held in private. The review model may therefore appear to be less transparent than its statutory counterpart. However, being held in private does not equate to being held in secret<sup>53</sup> and a robust and transparent process will provide reassurance and confidence in its findings.

79. Some basic questions should be considered when setting up a review, particularly one commissioned by a government Minister.

- ☐ How can independence be ensured when the investigation is usually commissioned by a member of the government?
- ☐ How can an investigation maintain its independence if the administrative support is provided by civil servants?
- ☐ What is the investigation “independent” from?

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<sup>52</sup> See, for example, AICPA Plain English Guide to Independence (2017) Available from: <http://www.aicpa.org/interestareas/professionalethics/resources/tools/downloadabledocuments/plain%20english%20guide.pdf> [Accessed 27 October 2017].

<sup>53</sup> Howe G (1999) The Management of Public Inquiries. *The Political Quarterly Publishing Co. Ltd* pp 294- 304 at p 302.

## The Mesh Review

80. When we asked members what ‘independence’ meant to them, there were a variety of responses. These would most appropriately be grouped in two ways. Firstly, some members understood independence in terms of the *individual* review member to assess the data and to follow it to whatever conclusions it led them to. For example:

*“I think an independent review is independent where there is a clear remit of what it is that has to be assessed, having set aside your own personal views, your own personal prejudices, your own personal sense of ‘I know what’s been going on here’.”*

*“Research doesn’t necessarily mean you are pro or against, you are fact finding.”*

81. Alternatively, other Review members emphasised the independence of the *process*.

*“Independent means unaltered by external forces”*

*“In this Independent Review and in other independent pieces of work I’ve been involved in, what it is designed to do is to have an externality about it. So it’s not us marking our own homework.”*

82. The former perspective envisions members as independent if they do not have pre-conceived views on the topic, or a predisposition towards a certain outcome. The latter perspective views a process as independent if it is not unduly influenced by the government. The two are not mutually exclusive characteristics, but are subtly different, e.g. a group could be objective but not separate from government, or wholly autonomous but filled with vested interests.

83. Independence of the chair is a central and necessary feature of any investigation.<sup>54</sup> He or she has to be able to secure the confidence of those with an interest in the process and its outcomes, whether they are victims, their families or the wider public.<sup>55</sup> Lack of faith in the independence of chairs has led to some inquiries being converted from a non-statutory review to a statutory inquiry. For example, the Independent Inquiry into Child Sexual Abuse was announced in July 2014 and converted into a statutory inquiry in March 2015.<sup>56</sup>

84. The members we spoke to agreed that the independence of the group as a whole would derive from the independence of the chair. In the context of the Mesh Review, this was seen as the chair being “independent of Scottish Government”:

*“A review draws its independence from how people use their skills, their expertise, their experiences, their analytical capacity to be able to answer a question that has been set for them to look at and that that can then be provided back in a way which is independent of whatever expectation from the originator. So the independence of person is then balanced by the independence of voice that comes back from the review chairman of the review group.”*

85. The different interpretations of independence also influenced whether members believed that the review process was or was not independent. Those who focused on the bias, or vested interests, of participating members tended to view the Group as not independent; whereas those who viewed independence as a separation from Scottish Government officials generally saw the process as independent. Although when they

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<sup>54</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies at p35 [Accessed August 12 2018]

<sup>55</sup> Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.16.

<sup>56</sup> HC Deb 7 July 2014 cc 23-27 & HC Deb 4 Feb 2015 C 275-277. This is also discussed in House of Commons Library (2018) Statutory commissions of Inquiry: the Inquiries Act 2005 Briefing paper no. SN064 10 at p.24.



were specifically challenged about this, for example, through the questions posed above, they were able to recognise the problems with the perception of independence.

86. There were some comments on the group being influenced by external forces such as the political interests, or media attention, and that this, in turn, influenced the independence of the Group. One observed: “*Outside attention [was] affecting what evidence was viewed as relevant, why and how to interpret it.*” Doubts were raised whether it is possible to create “*a transparent system with lay people that isn’t susceptible to politicisation through media or politics.*”

**We recommend that the chair identifies areas that may have the potential to compromise the independence of the investigation. This is part of his or her overall duty to ensure an effective inquiry process and public confidence in the outcomes and recommendations.**

### **Conflict of interest**

87. Conflict of interest, bias or undue influence may give rise to questions of whether independence is being compromised.

88. A conflict of interest may be defined as having judgement impaired or influenced by a secondary interest.<sup>57</sup> Whether or not the individual benefits or not, is irrelevant. Potential conflicts of interest are not an uncommon feature, particularly if the subject area is specialised, but a process should be in place to identify and measure them and to ensure that a proportionate response can be made. This is usually achieved through a declaration of interests.

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<sup>57</sup> National Audit Office (2015) Conflicts of Interest. Available from: <https://www.nao.org.uk/wp-content/uploads/2015/01/Conflicts-of-interest.pdf> [Accessed November 2 2017] at pp 4 – 6.

## The Mesh Review

89. This area gave rise to some of the most concerning findings of our Review. Within the membership of the Mesh Review were a number of potential conflicts of interest that should have been declared. Some clinician members had received payment to undertake clinical research. A patient representative had received payment for being part of a research project and was mentioned as an author on one of the key pieces of research considered as evidence in the Mesh Review.<sup>58</sup> Some members were the subject of litigation and others were suing. One of the clinician members was another Review member's surgeon.

90. All of these matters gave rise to potential conflicts of interest and should have been declared; but weren't.

91. Perhaps of greater concern was that, when specifically asked about these matters, some members did not immediately recognise how these issues could give rise to potential conflicts- it became clear that it has never been specifically discussed during the Mesh Review and that members individually had never been asked to consider such issues.

92. It is recognised that it would not be unusual for leading clinicians to be involved in research and their research sponsored by manufacturers in the area within which their specialism lay. Some members did raise this, making reference to the need for pragmatism in such a niche specialist area. Others highlighted the difficulty of getting expert insight without involving those with a vested interest in the topic. Instead they believed the focus should be on ensuring that interests in such a process are declared

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<sup>58</sup> Glazener C *et al.* (2016) Clinical effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study – results from the PROSPECT Study. HEALTH TECHNOLOGY ASSESSMENT 2016 VOL. 20 NO. 95 (SCIENTIFIC SUMMARY).

adequately, so that other members are aware of the positions and experiences an individual is bringing to the Group. However, this did not happen.

93. Depending on the nature of the subject matter under review, the fields of specialism may be particularly small, and it may not be unusual for a prospective reviewer who has extensive experience in their field to have professional or personal biases. These must, however, be disclosed. It should then be determined whether these biases would disqualify them as a prospective reviewer.

94. The test of “impartiality” may be usefully adopted.<sup>59</sup> This would address the problem of drawing and recruiting from a small pool of expertise and allow the recruitment of persons who have had prior involvement in the specialism and the subject matter of the review as long as this has been declared and a decision taken on the suitability of the prospective person in question. Impartiality was defined by some, as “*being objective*” and “*keeping an open mind.*”

95. Different cultures and organisations will approach this in different ways. Some will apply a rigid rules-based approach and others will adopt more flexible guidelines.<sup>60</sup>

**We recommend applying a test of ‘impartiality’. This would allow someone with prior knowledge or involvement in the subject matter to be a potential member on the basis that their involvement was disclosed and evaluated.**

96. It was not just expertise in the subject matter that was not declared. As stated, the fact that some members were involved in litigation was not discussed. We asked the first chair if she knew that one of the clinician members had been another member’s

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<sup>59</sup> This is also discussed in Department for Constitutional Affairs 2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] at p.14.

<sup>60</sup> A table can be found which compares a principles-based approach as used by the UK versus a rules-based approach which is adopted in the USA to manages conflicts of interest. Ibid at p. 19.

consultant and surgeon. The chair's response was *"I don't know, we never talked about that. It's not my business to know that. Those were personal things."*

97. A few members referenced on-going litigation involving members being avoided as a topic of discussion, with one member claiming they were explicitly not allowed to discuss the topic. However, they did not go into detail as to how this arose or who advocated such a position. A number of those we spoke to believed that it was the role of the chair to have identified those involved in litigation within the group.

98. Involvement in litigation, or a doctor patient relationship, has the potential to compromise the independence of any review. We believe that it was a major failing that these were not declared and discussed. The credibility or accessibility of outcome tends to determine public perception of independence. It is the role of the chair to address any issues which have the potential to compromise the independence of the investigation.<sup>61</sup>

99. One member stated that, in retrospect, they did not view the Group with the same degree of independence as they had done previously.

*"It struck me that it is quite impossible to get a review group that can ever make any meaningful recommendations that is actually independent of all relevant interests. I suppose it doesn't need to be independent, those interests just need to be declared. They never were, apart from the Final Report and they are limited."*

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<sup>61</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies at p.35 [Accessed August 12 2018].

## Declaration of interest

100. Independence of process can be scrutinized through a check list approach. The check list will contain a list of proscribed activities or circumstances under which independence may be perceived to be compromised.<sup>62</sup>

101. Conflict of interests or bias is much more concerned with reasons and motivations behind certain decisions or behaviour. It is concerned with internal thought processes rather than lists of prohibitions.<sup>63</sup> A system that recognizes both is required. A declaration of interest form may provide a checklist to address the former and as long as it is fit for purpose, it will do this adequately. However, something more, in terms of process, is required to address the latter; the individual's objectivity.

## The Mesh Review

102. In the Mesh Review, the request to complete a declaration of interests form came, via email, from various Scottish Government officials. The Chair assumed no oversight of this process. There were conflicting accounts as to whether individuals completed these forms or were able to see and/or discuss the declaration of interest.

103. For instance, one member stated that declarations were accessible and that people were asked at every meeting if they had "*anything new to declare*". Another said that they could see others' declarations but could not discuss them. One member said that they raised the issue of not being able to view others declarations several times and were only finally able to see other members' declarations when they were posted online.

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<sup>62</sup> ICAEW (2018) Independence v objectivity: What is the difference? Available from: <https://www.icaew.com/international-accounting-and-auditing/ethics-introduction-and-fundamentals/independence-v-objectivity-what-is-the-difference> [Accessed August 26 2018].

<sup>63</sup> ICAEW (2018) Independence v objectivity: What is the difference? Available from: <https://www.icaew.com/international-accounting-and-auditing/ethics-introduction-and-fundamentals/independence-v-objectivity-what-is-the-difference> [Accessed August 26 2018].

104. The fact that there had been no proper discussion of possible conflicts of interests which should have been declared became clear when interviewing the Review members. It was only when individuals were challenged on how their own professional background or interests could give rise to a potential conflict that this was recognized. A number of those interviewed indicated at the beginning of our interviews that they were entirely independent but then conceded that there may have been conflicts of interest which they had not considered, and which would, to an outside observer, give rise to criticisms of bias or conflict.

105. For those who did complete a declaration of interest form, the majority said that they had done so at least twice and sometimes three times; however this may not have been accompanied by an explanation of why this request was being made. One member believed that some of the initial declarations were carried over from their time on the Short Life Working Group. *“I lost track of what I was signing the form for.”* Another said: *“I really didn’t feel that the process that was in existence was at all satisfactory.”*

106. Many members had serious reservations as to the appropriateness and format of the declaration of interest form used and because of this they volunteered more information than they were asked to on the standard declaration of interest form.

107. There were a number of concerns expressed. First, the form only asked for activity for a retrospective period of 12 months. The form that members were given was not fit for purpose, providing no prompt or opportunity to make a full and meaningful declaration of interests.

108. This was a major omission. Research interests, payments for clinical trials, co-authorships and involvement in litigation should all have been declared. A 12 month “snapshot” of relevant interests was insufficient.

109. A second concern was the lack of breadth in terms of the different vested interests a person might have. For example the form only asked for information on what it referred to as “commercial interests.”

*“It was only about industry, so it didn’t ask about other conflicts of interest or other competing interests or other vested interests that are not money related.”*

*“The other thing about declarations is there’s a lot of conflict about what industry gives you but I think that the intellectual conflict is sometimes more important.”*

110. Some suggestions were made to us that the declaration of interest form should have provided space to write a short commentary which may assist with putting declared information into perspective. We believe this would have been useful as it would have provided an opportunity to exercise judgment and declare what members thought would be relevant to protect the independence and integrity of the review.

111. Third, the form only covered the individual in question, and it did not enquire about the interests of family members or partners.

*“I have to say I was very concerned about the form that I was given which is totally unfit for purpose. I was asked to fill it out before I attended the first meeting and because I was so unhappy about its content I made a fairly lengthy statement of previous interests at the first meeting I attended.”*

112. The completed forms were added onto the Scottish Government website. However, this appears to have been done in a piecemeal fashion with some additions and amendments continuing to be made up to as recently as April 2018.

113. Concerns were expressed by members that the declaration of interest forms were removed from the website for those members who resigned. This prompted one member who had resigned to contact the Scottish Government requesting their declaration of Interest form be put back on to the website.

114. Independence of process and membership of the Mesh Review have been among the most contested areas during our investigation, both during the Review and following the publication of the Final Report. The process for declaring relevant interests was inconsistent, leaving members unsure what they were declaring and why. The actual form did not assist with this process with some members providing additional objective information and others submitted no forms at all on any occasion.

115. The fact that the chair expressed the view that it was not her – or the members’ – business to inquire about matters of research interests, litigation and potential conflicts where a doctor and their patient were both members of the Review may explain why the process was so poorly managed. Finally, the process for putting declaration of Interest forms on the Review website seems haphazard and confused, particularly where it involved the resignation of a Review member.

116. It would have been useful that there should be clarity about the process for requesting the completion of declaration of interest forms. For example, members should be advised about the form, whether there is accompanying guidance and how often such a request should be made. It should be explained how and where they are to be stored and whether they are publicly available.

117. A declaration form should have accompanying guidance or prompts to address questions of potential conflict of interest. This places the responsibility of declaration on the member and introduces a flexibility and opportunity to apply ethical judgement. Both the checklist element and ethical elements would then be satisfied.

**We recommend that a process should be in place to identify and measure potential conflicts of interest to ensure that a proportionate response can be made.**



**We recommend that the chair has responsibility to lead the members of the review in discussion to consider possible conflicts of interest.**

**We recommend that the importance of transparency and accountability in the completion of Declaration of Interest should be explained as part of a general induction process.**

## Chapter 4: The selection/appointment and responsibility of the chair

118. Recruiting a chair should be an open process, and reasons given as to why the chair was considered suitable. Candidates should be interviewed and assessed against relevant criteria which will test their suitability to chair the subject matter under review include an assessment of whether the chair has previous experience.

119. The chair is the lead person in any investigation.<sup>64</sup> He or she should set the tone and be the final arbiter on all aspects of the outputs arising from any investigation or review.<sup>65</sup> A good chair requires extensive skills; including integrity, leadership and the ability to analyse and critique.<sup>66</sup> Attributes such as career background, expertise and reputation should also be considered as these will have an impact on issues such as conflict of interest, bias and independence.<sup>67</sup>

120. A successful chair needs to be a good communicator and be aware of diverse stakeholders' interests, both internal and external to the review. The process to appoint the chair and the reasons for choosing him or her should be clear and be publicly available. In practice, there is very little guidance available on how such appointments

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<sup>64</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies at p.12 [Accessed August 17 2018].

<sup>65</sup> Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.15.

<sup>66</sup> Centre for Effective Dispute Resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies at p.12 [Accessed August 17 2018].

<sup>67</sup> Levitt, R & Solesbury W., (2012) Policy tsars: here to stay but more transparency needed. Final report. Kings College, London at p.2 Available from: <https://www.kcl.ac.uk/sspp/departments/politicaleconomy/research/Current-Research-Projects/tsarsreport/Tsars-Final-Report-Dec-2012.pdf> [Accessed August 18 2018].

should be made.<sup>68</sup> The reality is that often the chair's appointment may need to be announced quickly, even if it is to the detriment of more measured appointment process. Sir Robert Francis QC, Chair of the Mid Staffordshire NHS Foundation Trust Public Inquiry<sup>69</sup> observed:

“As far as appointment is concerned, like most chairmen, I had the experience of being phoned up out of the blue and asked to decide within an hour whether I would like to chair the inquiry because the Minister was in a hurry to make an announcement. I am frequently asked, probably with some surprise, ‘Why were you chosen?’ I have absolutely no idea, or about the process.”<sup>70</sup>

## The Mesh Review

121. For the Mesh Review, the only specification from Alex Neil was that the chair should be a “retired public health consultant.”<sup>71</sup> There was no reason given as to why the chair had to come from this career background. No other attributes were mentioned. This seems ill-considered and arbitrary.

Initial contact with the first chair was made by telephone by the Acting Deputy Medical Officer. She was still considering whether to undertake this role “*when the Minister announced the appointment.*” This was her first time chairing a Government Review.

122. This was a remarkably arbitrary approach to take towards appointing a candidate to chair a review, the subject matter of which had already attracted and would continue

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<sup>68</sup> Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.16.

<sup>69</sup> Available from: <http://webarchive.nationalarchives.gov.uk/20150407084231/http://www.midstaffspublicinquiry.com/report> [Accessed September 10 2018].

<sup>70</sup> Francis R (2013) Oral Evidence to the House of Lords Select Committee on the Inquiries Act 2005, House of Lords, Q205 cited in Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.15.

<sup>71</sup> [http://www.parliament.scot/S4\\_ChamberDesk/WA20141029.pdf](http://www.parliament.scot/S4_ChamberDesk/WA20141029.pdf).

to attract a high level of public, political and media interest. It seems rather a lot to expect someone who has never previously chaired a Government review to take on such a challenging role.

123. To be able to effectively lead the process, it is the responsibility of the chair to understand and be able to address the strengths and weaknesses of the other members. In the Mesh Review, the first chair proposed the appointment of only one member, which was accepted. All other appointments, up until that time, had been made prior to her becoming chair. She had no involvement in that process and, as we have previously identified, little knowledge or wish to consider possible conflicts in members' interests.

124. Following the first chair's resignation, the second chair's initial invitation came via telephone, from an official from within the office of the Chief Medical Officer. The second chair received the invitation with some caution as she was about to undertake a new role and was unsure whether she would have the time to make the commitment. She was advised by Scottish Government officials that the duration of the work would be approximately 6 to 8 weeks and there was strong emphasis that her role was one of taking a report "*over the line*." The report was described to her as "*virtually complete*" and "*all ready to go*." On this basis she assumed that there was little work left to complete.

125. She did not fit the original chair specification as she was not retired. Her appointment as a Medical Director with the National Health Service Scotland, of itself, raised concerns about a possible conflict of interest. No discussions took place to explore this, nor was there any consultation with Group members. The matter of whether her background and current role compromised the independence of the chair remained unresolved.

126. When the second chair attended her first meeting, many members of the Review were unaware of a change in Chair or who she was. The minutes from that meeting do not reflect any introduction.<sup>72</sup> When we questioned the lack of a minuted introduction for the second chair, a government representative conceded that it was an example of “*poor management*.”

127. The second chair was not informed of the reason for the departure of the first chair. There was no offer made to meet the first chair or for any handover process. There was no communication between them at all.

128. There was also no process in place to deal with resignations whether from the chair or any other member. The commissioning parties of a review should ensure that the suitability and impartiality of the group continues throughout the investigation and be prepared for eventualities such as the resignation of the chair or members.

“A chair or panel member may die or may need to withdraw suddenly, and decision about whether to replace, and with whom, need as much care as the original appointment. The appointing Minister has a continuing responsibility to ensure efficiency, probity, public accountability and confidence in the process.”<sup>73</sup>

129. We recognise that it may not always be an easy task to encourage candidates to put themselves forward to be considered to undertake a task of this nature. Being able to recruit a competent chair with the correct analytical skills and judgement is not without its challenges.

130. In the Mesh Review, the method of appointing the chairs was undefined with no appropriate governance applied to either appointment. The appointments were neither

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<sup>72</sup> Monday, January 23 2017.

<sup>73</sup> Northern Ireland Human Rights Commission submission to Department for Constitutional Affairs (2004) Response to Consultation [CP (R) 12/04] 28/09/2004 Effective Inquiries - Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] atp.15.

open nor transparent. The first chair believed she was still deciding whether to accept the role when her appointment had been confirmed to the Scottish Parliament.

131. There was no evidence that the Scottish Government officials tasked with choosing a chair had done any form of research into what skills the role required and who may be potential candidates. Once appointed, the first and second chair appeared to have been given very little information on what was required of them and even less guidance on how they should carry out the role. Once in the role, their actions appeared to be directed by information from Scottish Government officials, rather than exercising the autonomy that the role required. In hindsight both chairs agreed that they could have been more proactive.

132. Finally, there was no process to ensure a handover from the first to the second chair. There was no procedure or planning to address the situation where a chair may resign.

**The appointment process to select the chair should be transparent.**

**We recommend that the commissioning party should ensure that the chair possesses skills specific to the nature of the inquiry.<sup>74</sup> The commissioning party should also have a continuing responsibility to ensure that the chair promotes accountability and confidence in the inquiry process.**

**We recommend that support and some sort of induction, including background materials<sup>75</sup> be given prior to undertaking the role. The former is especially important if the prospective chair is undertaking the role for the first time.**

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<sup>74</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from:

<http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf>

[Accessed November 7 2017] atp.15.

<sup>75</sup> Id.

**We recommend that a system of mentorships be established and a pool of those who have had experience chairing a Government review be available to draw upon to support a novice chair.**

**We recommend that potential appointees have no perceived conflict of interest which may raise doubts on impartiality and independence.<sup>76</sup>**

**We recommend that the chair should be involved in the selection process of potential review members.<sup>77</sup>**

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<sup>76</sup> Centre for effective dispute resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies at p.14 [Accessed August 17 2018].

<sup>77</sup> Centre for effective dispute resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies at p.15 [Accessed August 17 2018].

## Chapter 5: Selection and composition of members of a review

### Selection of panel members

133. There is no obligation to appoint panel members to a review, but if such appointments are made they raise similar questions to that of the chair, namely; selection process, composition, responsibility and independence.

134. Recent Scottish examples show there is scope for a varied approach towards composition. For example, The Independent Advisory Group on the Use of Biometric Data in Scotland comprised ten members,<sup>78</sup> The Hate Crime Legislation Review, nine members,<sup>79</sup> The Commission on Women Offenders, three members.<sup>80</sup>

135. The predominant consideration should be the requirements of the review. What skills and experiences are required for it to be able to fulfil its remit?

### The Mesh Review

136. The Final Report of the Mesh Review lists 26 members.<sup>81</sup> In response to a parliamentary question<sup>82</sup> concerning terms of reference, membership and criteria for

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<sup>78</sup> The Independent Advisory Group on the Use of Biometric Data in Scotland, chaired by John Scott QC. Terms of reference and membership details available from: <https://www.gov.scot/Resource/0052/00522483.pdf> [Accessed August 19 2018]

<sup>79</sup> The Hate Crime legislation Review, chaired by Lord Bracadale. Report available from <https://www.gov.scot/Resource/0053/00535892.pdf> and membership of the reference group detailed on p.3. [Accessed August 19 2018]

<sup>80</sup> The Commission on Women Offenders, chaired by the Right Honourable Dame Elish Angiolini DBE QC. The report is available from: <https://www.webarchive.org.uk/wayback/archive/20170107101909/http://www.gov.scot/Resource/0039/00391828.pdf> and membership detailed on p.14.

<sup>81</sup> The Scottish Government (2017) Final Mesh Report at p.102.

<sup>82</sup> Neil Findlay (Lothian) (Scottish Labour): To ask the Scottish Government what the terms of reference are for the independent review of the safety of mesh devices; who the members or the review group are; what the criteria for



membership for the Mesh review, Alex Neil, the then Cabinet Secretary for Health and Wellbeing who commissioned the Mesh Review, responded as follows.<sup>83</sup>

“Membership of the group is reviewed periodically, and additional members invited to attend when necessary. This is to ensure the appropriate level of expertise and range of opinion is represented. The composition of the group has been developed to represent all interested parties, including:

- One chairperson (retired public health consultant);
- Two patients who have experienced complications;
- Two patients who have experienced a positive outcome;
- Four clinicians with a special interest in urogynaecology practicing in Scotland;
- One public health consultant;
- One researcher;
- Three professional bodies;
- Three Scottish Government officials (two clinicians and one policy officer);
- One medicines and healthcare products regulatory agency official.

Members attending periodically:

- One physiotherapist;
- Two clinicians (unique device identifier project lead);

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membership are, and whether it considers that the composition of the group represents a fair range of views. (S4W-22683) Available from: [http://www.parliament.scot/S4\\_ChamberDesk/WA20141029.pdf](http://www.parliament.scot/S4_ChamberDesk/WA20141029.pdf).

<sup>83</sup> [http://www.parliament.scot/S4\\_ChamberDesk/WA20141029.pdf](http://www.parliament.scot/S4_ChamberDesk/WA20141029.pdf).

- One Scottish Government public health consultant.

Members to be confirmed:

- One pain management consultant;
- One general practitioner;
- One clinician with a special interest in urogynaecology;
- One Information Services Division consultant in public health.”

137. Compared to the approach taken in other reviews, this seems an unusually large core number which would have been difficult and unwieldy to control for an experienced chair. This would have been more challenging for someone who had not previously undertaken the role of chair in a Scottish Government review.

138. Based on the member list contained in the Final Report, the additional clinicians who were to attend periodically were not appointed.<sup>84</sup> Four clinicians were listed and one of these had resigned by the time the Final Report was published. There were also no pain management or general practitioner appointments.

139. In terms of patient representatives, the requirement for (a) two patients who had experienced complications and (b) two who had experienced good outcomes were initially met. However, one of the patient representatives with a positive clinical experience of mesh only attended the first meeting and was not replaced. This gave rise to many concerns about patient representation being unbalanced. This was never remedied.

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<sup>84</sup> The Scottish Government (2017) Final Mesh Report at p. 102.

140. The petitioners did not regard themselves as being part of the collective of patient representatives. Instead they saw themselves both as petitioners and as representatives of the Scottish Mesh Survivors Group.<sup>85</sup>

141. Earlier reference has been made to the Short Life Working Group which had been in existence since 2013.<sup>86</sup> An Expert Group evolved from this and held its first meeting in February 2014. It was generally agreed that the work of the group had been very positively received. Some who were members of that group became part of the Mesh Review Group, including the patient representative with a good outcome and the petitioners.

142. One member who became a member of both believed that this was a “*sensible*” approach. Another member’s perception was that the main difference between the Expert Group and the Mesh Review Group was “*a change of chair*”. A few of the Group continued their membership with both the Expert Group and the Mesh Review.

143. The Expert Group agreed to suspend its work whilst the Review was being conducted, although some members told us that, occasionally, update meetings were held on the same day that the Mesh Review meetings were held.

144. One member commented that they felt people “*volunteered*” to be part of the Mesh Review group from the Expert Group rather than being selected, observing “*it was a kind of internal nomination ... but I don’t exactly know the process.*”

145. Others were invited to become members of the Mesh Review because they represented organisations which may have had an interest or expertise in the subject.<sup>87</sup> It was recognized that the pool from which to draw expert representation was not a large one:

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<sup>85</sup> <http://www.scottishmeshsurvivors.com/>

<sup>86</sup> The Scottish Government (2017) Final Mesh Report at p.7.

<sup>87</sup> This would include, for example, Royal College of Obstetricians and Gynaecologists, British Society of Urogynaecologists, Specialists in Public Health etc.

*“All of us have had some involvement in something at some point on a national level because there aren’t that many of us.”*

146. Finally, additional members were proposed. This seemed to arise due to dissatisfaction with the composition of the membership of the Review. These additional suggestions were an attempt to bring what has been described as “*balance*” to the Mesh Review Group, usually following a request from an existing member. One such example references the petitioners advocating for the inclusion of a surgeon from the USA. His inclusion was ultimately deemed unsuitable. However this resulted in an additional clinician co-opted into the Mesh Review Group.

147. Members were asked if they were provided with any guidance on how the Mesh Review Group or any comparable group should operate, and how they could best fulfil their role as a member of such a review group. They all said that they had not received any form of guidance. The majority felt that drafting guidance for members of reviews would be beneficial and may mitigate some of the issues the Mesh Review Group experienced.

*“I would have welcomed this. It’s quite a formidable thing to be asked to sit on something like that.”*

148. Members of the Mesh Review appear to have been recruited by various means. A few participants reference the Scottish Government as being the main force in the selection and appointment of the group members. However there appears to be disagreement as to who specifically had responsibility for the selection of members. Some members were initially contacted by telephone; others by email.

149. Despite a list detailing the proposed membership of the Review having been presented to Parliament, this was not adhered to. This was especially evident in the

patient representation where there were two individuals – the petitioners – who had experienced adverse outcomes and saw their specific duty as representing the organisation to which they belonged and to uphold their submission to the Public Petitions Committee. Viewed in this way, the patient representation criteria were not fulfilled at all.

150. It seems clear that the composition of the panel was reached in a largely arbitrary manner. This may be due to the fact that there is no ‘standard’ approach for the selection and appointment of group members in Ministerial reviews. An initial membership seemed to evolve from a pre-existing Expert Group, professional representation was invited and then additions were made to appease some dissatisfaction with the composition of the group. Apart from one member, the first chair appeared to have no direct role in the selection or appointment of members of the Review. There was also a misunderstanding in terms of the representation of those who attended as patients.

**We recommend that guidelines should be developed detailing the procedure which is required to establish an independent review. These guidelines should be in a form which can be modified and standardised over time. We believe that the more widely used they become, the more accepted they become.**

**We recommend that the process for the selection of members should be as independent of the subject or area under review, as possible. We recommend that criteria should exist to determine the composition and balance of review members in relation to the subject matter under review.**

**We recommend that the chair should be the first appointment and that members should be either selected by the chair or in consultation or approved by the chair.**

**We recommend that the degree of external control of a review may also have to be considered within the – sometimes competing – interests of constraints on**

**time and costs. The process for evaluation and selection should be transparent and accountable and if possible, undertaken by someone outwith the area or subject being reviewed.**

### Composition of members of a review

#### Special interest or third sector representation

151. Special interest or third sector representation is recognized as a unique resource and distinct from professional or clinical skills and input.<sup>88</sup>

152. We explored what members thought about having ‘special interests’ representatives as part of the Group. We have defined ‘special interests’ as persons with direct involvement, for example, patient representatives on a health related review or victim representatives on a criminal justice related review.

153. One of the biggest decisions to be taken in the composition of a panel is whether those who have been directly affected by the subject under review should be core members of a group and/ or whether there should be ‘third sector’ representation.

154. For example, in the Mesh Review, this could have been someone from an organisation representing patient interests, but having no direct, personal experience of the subject matter themselves.

155. The benefits of having this type of composition may include bringing balance to discussions but it has been suggested that such representation should depend on the nature and needs of the particular investigation.<sup>89</sup>

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<sup>88</sup> Baxter S, Clowes M *et al.* (2017) Supporting public involvement in interview and other panels: a systematic review. *Health Expectations* 20 5 807-817 at p.807 Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5600233/> [Accessed August 19 2018]

156. When asked, the majority of members were enthusiastic about the idea of having a representation from a third sector organization.

*“They would need to have an understanding of the level of literature, etc. but they also need to be able to work with individuals who are not from that area but would put special time aside to help them go through the materials but not have a vested interest. Be totally outside it. Ask them what their views are and reflect with them.”*

*“Without a shadow of a doubt, I think there needs to be lay representation. And I think that there should be lay representation to reflect the opinions of both groups.”*

157. Some members had experience of having third sector representation in other reviews and found this beneficial.

#### The Petitioners as members of the Mesh Review

158. A few members believed that the petitioners “had” to be included in the Review, one commented that the “*petitioners being at the heart of the process*” gave it “*power*”. Another felt that the results of the report would have “*issues of legitimacy*” if the petitioners had not been part of the process.

159. Others commented on feeling that the petitioners had an undue weight within the group feeling that “*the process was for them and dictated by them*”.

160. Some members recognized that the petitioners were representing not only their own experiences but those of the organization to which they belonged; the Scottish

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<sup>89</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. p. 19 Available from: <http://webarchive.nationalarchives.gov.uk/+http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed August 19 2018].

Mesh Survivors. Others believed that the petitioners viewed the Review Group's function as a means to *"find evidence that would lead to the banning of mesh."*

161. Everyone we spoke to held the petitioners in high regard and acknowledged their significant efforts in getting the topic higher levels of media and political exposure, and fostering discussion on the topic.

*"They have got the whole system changed for documentation, they have got a whole new consent system, they've got doctors sitting and listening, they've got the GP's listening. There are marvellous things that have come out because of what they have done... If you look at the success that they have achieved through campaign, it's wonderful."*

162. The work the petitioners conducted as part of the Expert Working Group in terms of changes to information leaflets and doctor/patient dialogue was also commended. Some feared such positive impact had been reduced or *"lost because the focus moved to the outcome of the[Mesh] Review and the tensions that surrounded it."*

163. Another member acknowledged her difficulty in trying to reconcile personal emotion, the Review process and wider government and public interests:

*"You have women who are understandably really angry about their lives and their life projection ... When you have the Government interests, and all of these are antagonistic to one another and it's raw and it's hard and then you have an academic process to go through as well. So not only have you got emotions that have to be cut short...but you have a process that has to be written about in a particular format which is alien to empathy and understanding of how someone would naturally access information."*



## Direct patient involvement

164. There was less consensus on whether the inclusion of patients directly affected by the topic under discussion was a usual or appropriate arrangement. Some members stated a preference for hearing evidence from patients via subgroups.

*“I think seeing the patient groups as part of a sub-committee that then reported back, but reported back appropriately, was probably the way to go forward, because there was quite a lot of stalling [in] my experience in those meetings that prevented the meetings being as effective as they could have been. That’s not to say they weren’t effective, but they could have been more effective.”*

165. Others felt that direct patient involvement was necessary and valuable. Some participants questioned the likelihood of not involving patients directly in high level governance groups due to concerns such an omission may affect the legitimacy of the group itself, and any subsequent reporting.

*“Not at all. I think the fact that they were full and active and listened to members, and I talk about all three of them here, of that committee was absolutely vital to the function of that committee.”*

166. Others noted that it depended on what “type” of review it was and what process what adopted.

*“No. I think you would have taken evidence from them. You would ask them to come and speak to you, wouldn’t you? But it wasn’t really set up as a take evidence type of Review. It was really set up as a clinical type of Review, that’s what lured me into thinking that’s what its purpose was. Look what evidence is out there, decide how you are going to make recommendations from that and put it into a document.”*

167. We found this insightful because clearly this member was not alone in their perception that this was a “clinical” review. We believe that such a discussion as to what type of review it was did not take place and consequently, this may have had a bearing on how members regarded and interpreted the evidence.

168. We believe that it is a question of the nature and requirements of a review as to whether there should be representation from patients who have been personally involved. The terms of reference and remit should provide direction in the composition of a review. Patients as mirrors of perception or experience can contribute a powerful voice, and their membership may not only provide experience but insight and legitimacy.<sup>90</sup>

169. In a health related review, the degree of involvement that a patient representative will have, should be taken into consideration in preparation of background materials and ongoing support.<sup>91</sup>

**We recommend that an evaluation of the merits of having special interest representation in a review should be guided by the nature and requirements of the review.**

**We recommend that alternative approaches be considered in whether it is more appropriate to have this representation as part of a sub group with an effective spokesperson to feedback discussion to the core group.**

170. Whilst other members appeared to be more familiar with the direct patient involvement approach, this was most apparent in those who worked with or for the

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<sup>90</sup> Patient Voices, Insight through first person stories. Available from: <https://www.patientvoices.org.uk/> [Accessed August 19 2018] see also, Heath S, (2017) How to Integrate the Patient voice into Healthcare Decision making. Patient satisfaction news. Available from: <https://patientengagementhit.com/news/how-to-integrate-the-patient-voice-into-healthcare-decision-making> [Accessed August 19 2018].

<sup>91</sup> Baxter S, Clowes M *et al.* (2017) Supporting public involvement in interview and other panels: a systematic review. *Health Expectations* 20 5 807-817 at p. 808 Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5600233/> [Accessed August 19 2018].

NHS.<sup>92</sup> However, it was noted that any such increased patient participation was usually accompanied by training and support.

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<sup>92</sup> There is a large body of literature on this. See, for example, Mockford C, Staniszewska S *et al* (2011) The impact of patient and public involvement on UK NHS health care: a systematic review. *International Journal for Quality on Healthcare*. Available from: <https://academic.oup.com/intqhc/article/24/1/28/1803627> [Accessed 19 August 2018]

## Chapter 6: Role and conduct of the chair and members of a review

171. The subject matter of a review may often be a difficult and emotional one. This is especially so when members of those giving evidence may have been directly affected by the subject under investigation<sup>93</sup>. For others, it may also be cathartic and offer closure just to be able to have the opportunity to discuss their experiences. External influences, such as the media, political interests or responsibilities to organizations and professional groups may also bring added pressure or emotional stress.

172. If any of these elements are likely to be present in a review, then consideration should be given and, where required, necessary adjustments made, for example, resources and support groups being made available to those involved. Failure to address this can affect perceptions of fairness, trust and objectivity. It is the responsibility of the chair to recognize, respect and respond.<sup>94</sup> This once again highlights the need for the chair to have excellent communication skills.

173. A good chair needs to command the respect of his or her members. He or she should have a clear understanding of the remit of the group and the roles of the members in seeking to achieve that remit. Clear and detailed direction needs to be provided to the group in relation to the scope of any review, the timescale and the

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<sup>93</sup> Centre for effective dispute resolution( 2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from:

[https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p38 [Accessed August 17 2018]

<sup>94</sup> Centre for effective dispute resolution( 2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from:

[https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p38 [Accessed August 17 2018]

outcomes. The chair needs to be able to address issues over possible bias or conflict. 174. They set the tone on how the meeting will be conducted. The chair is the 'front face' for the public and media, becoming synonymous with the review which is often evidenced by the review being referred to by the surname of its chair.

## **The Mesh Review**

### **Role and conduct of the chair**

175. Many members of the Mesh Review acknowledged the challenges of chairing the review. One member described the first chair's appointment and role as an *"impossible task."* *"I think it was very, very difficult for the chair(s), at times, to keep control."*

176. Most of those we spoke to distinguished the styles between the first and second chair. The majority of participants alluded to the attempts of the first chair to build consensus around topics and ensure members' voices were heard. *"She wanted to ensure that the balance was being sought and that where possible consensus could be achieved."*

177. Other members felt that the first chair took a different approach depending on who was speaking and, in particular, rather than taking pro-active steps to bring conflict within the Group to a constructive conclusion, allowed it fester. Conflict was indulged rather than being resolved. This often led to protracted disagreement. Another commented that the chair did not *"manage the impasse"* and that conversations would often become *"emotionally charged"*. One member commented that the chair *"did as well as she could"*, but *"trying to please everyone was never going to work given the adversarial nature of the dynamic."*

178. There were four resignations; the first chair, Dr Wilkie; a clinician member, Dr Agur and the two petitioner members, Elaine Holmes and Olive McIlroy.

179. There was general surprise at the resignation of the first chair.

*“I didn’t know why [the first chair] wasn’t there at the last few meetings. She just wasn’t there, and the new lady said, ‘I’m the new chair’ and I thought, oh well that’s a bit odd.”*

180. No one was informed as to why the first chair had resigned beyond an allusion to “*personal reasons*” or to the project lasting significantly beyond the initially agreed 6 to 12 months’ timeframe.

181. When the second chair took over, the majority of comments we received referenced a sense of “*urgency*” to conclude the work of the Mesh Review Group and publish the Final Report. Over two years had passed since the first meeting. Ten months had elapsed since the publication of the Interim Report. The environment that the second chair came into was a very different one from the one experienced by the first chair.

182. The petitioners tendered their resignation at the beginning of the first meeting of the second chair, although she persuaded them to stay. They subsequently resigned after that meeting. The expert clinicians were failing to agree on the contents of the chapter that they had been tasked to write- Chapter 6 - resulting in Dr Agur indicating that, as a consequence, he may tender his resignation.

183. After several phone calls with Dr Agur with no resolution, the second chair contacted his line manager. When we asked her why she chose to do this, she spoke of concerns over professional competence, and stated that it was “*standard procedure*” in their organisation. Dr Agur viewed it as “*using line management to exert pressure and to coerce and bring that person back into line.*”

184. When challenged to consider whether her actions were appropriate, the second chair accepted that it may have been an overstepping of bounds.

185. The second chair's decision to contact the line manager of one of the clinician members was inappropriate. Even if this was done with the best of intentions, including any concerns that she may have had over his professional competence, it showed a lack of judgement and lack of respect for professional boundaries.

186. There seems to have been no process or agreement on how to manage a situation if a member of the Review wished to resign.

187. Following the resignations, it would have been prudent to discuss whether the Mesh Review Group was still sufficiently quorate and representative to allow it to continue its work. Whatever the outcome, that conversation should have taken place and been minuted.

188. Resignations should have been first intimated to the Chair. Members of the Mesh Review should have been informed of a resignation rather than hearing it from the media.

**We recommend that a process be established to manage any changes to the membership of a review. The process should include matters such as intimation of any resignations and consideration of replacements and quoracy.**

189. Although identifiably different in style, both chairs appeared to have been unclear and lacking in guidance as to the nature of their role. The first chair accepted the role having had no involvement in the drafting of the terms of reference or selection of members. Matters regarding possible bias or conflict remained unresolved. She was regarded as having a more empathetic but inconsistent approach whereas the second chair's approach was perceived as being more structured, but urgent. This is unsurprising given the circumstances of her appointment which emphasized a short timescale within which to hold meetings and pressure to produce a Final Report.

## **Role and conduct of members of a review**

190. How an investigation is to be conducted should be made clear to all members. The lead and tone should come from the chair. Consideration should be given as to whether the discussions are to be held in confidence and how to promote conduct that is agreeable to all members and conducive to the progress of the review.

191. Members should be chosen in an open and transparent manner. They should be chosen for their knowledge and experience in relation to the subject matter concerned.

192. Conduct should be agreed around a set of values or principles such as the Nolan Principles. These principles were established in 1994 following the UK government's creation of the Committee on Standards in Public Life.<sup>95</sup> These seven principles are generic in nature; selflessness, integrity, objectivity, accountability, openness, honesty and leadership. They may serve as a starting point to agree how any review group is going to proceed and the terms within which it will operate.

193. A second important consideration is the nature of the investigation. Is it to be simply a fact finding mission or one which is required to apportion blame for any faults or omissions? Adversarial elements may often emerge in a review where matters of criticism or apportionment of blame arise.<sup>96</sup> This is not unusual and often hard to avoid:

“Whenever some disaster befalls the human race, the instinctive reaction of most people is to seek its cause and try to prevent a reoccurrence. But behind this

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<sup>95</sup> Leading governance (2013) The Nolan principles-20 years on... Available from <https://www.leadinggovernance.com/blog/nolan-principles-20-years> [Accessed August 29 2018]

<sup>96</sup> Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. p. 30 Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed August 19 2018].



civilised response there lies a darker motivation as old as time- the urge to lay blame.”<sup>97</sup>

## **The Mesh Review**

194. During the first meeting of the Mesh Review group, it was minuted that the Review would be conducted in “an atmosphere of trust and openness, where transparency would underpin open discussion in the knowledge that the participants may do so in confidence.”<sup>98</sup>

195. Members of the Mesh Review were not guided as to whether their approach was to be inquisitorial or adversarial. More generally, members were uncertain about and referenced a lack of guidance on what they were expected to do as a member of the Review.

*“What are the behaviours that are expected? What are the things that are not? What to do if you run into trouble or how to treat the Scottish Government officials. What is their role in this? None of this was clear.”*

196. Many described situations or themes that were characteristic of a breakdown in communication during the operation of the Mesh Review. These issues ran from interpersonal misunderstandings to administrative issues; organisational and cultural clashes, and a lack of guidance on process and timeframe.

197. A recurring problem was the belief that consensus had been reached during a meeting only for the issue to subsequently arise again, apparently unresolved:

*“You would make progress on the phone and then it went away. You would make progress by sending documents round and then it would go away again. We had*

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<sup>97</sup> Howe G (1999) The Management of Public Inquiries. *The Political Quarterly Publishing Co. Ltd* pp 294- 304 at p 296, quoting Sir Cecil Clothier QC.

<sup>98</sup> Minutes of Meeting 1, Monday 21 August 2014.

*a conference call when we reached agreement then that was subsequently rescinded. Very difficult to keep track of that. No idea of what might have been going on as a sort of second play between individuals in the Group.”*

198. There was speculation as to the cause of the shifting nature of group consensus, particularly between meetings. Suggestions included members not feeling fully “comfortable” to challenge what was under discussion. Others told us that this was due to the short period of time lay members of the Group were given to “get to grips” with the material, which in turn affected their ability to question the material in meetings.

199. Administrative issues took up a lot of time that some members believed could have been more usefully deployed to progress the agenda. An example of this was protracted discussion over the content and lack of agreement of the minutes. This was a recurring concern, “*If people felt that there was something in a minute they disliked they would contest it.*” Another observation was that people “*were communicating on different wavelengths*”.

200. Particular reference was made to one meeting that ended early due to tensions running high.

*“It became driven by making sure everybody stayed in the room and talked not shouted and didn’t get up and walk out and didn’t actually insult people to their faces and keep level of anger down. I’m not talking specifically about one group here, to try to get progress. I have never been in more difficult meetings and never wish to again.”*

*“We had meetings which we had to stop because members were crying and had to leave the room.”*

201. As the pressure to find consensus and produce the Final Report increased, the emotional elements and lack of compromise appeared to become more acute.

*“I was surprised at what lack of trust there was, even within the room.”*

*“You had one extreme opinion saying every device is alright and [some] patient campaigners on the other side saying everything is not.”*

*“That was the difficulty that I thought we were having is that the Group was saying one thing and we were all trying to look at the evidence, come up with a reasonable compromise and a reasonable way forward but we had a group who were like ‘no’ there is no compromise. There is no way forward and there was no discussion. You can discuss things and agree to disagree but there was no discussion.”*

202. The adversarial atmosphere, during the group’s meetings, was mentioned by most of those we spoke to. It posed a broader question of whether reviews should be solely investigative or whether there is a place for the more adversarial discussion occasioned here.

203. Despite the agreement during the first meeting that the Group would proceed in an atmosphere of trust and openness, divisions between members of the Group emerged from the outset of the meetings. One meeting ended early due to some members leaving the meeting early, feeling unable to continue.

204. Despite the individual frustrations and tensions, one thing that came through strongly from those to whom we spoke, or received evidence from, was a clear sense of duty or citizenship. Each member had agreed to being part of the Review in a spirit of citizenship and goodwill and saw it as their “*responsibility and duty to give of [their] time*”, often alongside other extensive commitments.

**We recommend that a review should agree, at the outset, what it is seeking to establish and the methodology of how this can be achieved. Whilst we would**

**anticipate that an investigative/inquisitorial approach may be the norm<sup>99</sup> it would depend on the nature and requirements of the review.**

### **Role and participation of Scottish Government officials**

205. Some comments were made by members concerning the fact that it was the Scottish Government officials who set the agenda. In the early meetings, this seemed to have been done in collaboration with Group members. If members wished to include a paper for discussion, then this would be forwarded to the Government secretariat. The later meetings, following the publication of the Interim Report, seemed to lose direction in terms of how the agenda was compiled and how a request from a member to have an item included for consideration would be addressed. Time pressure would have contributed to this but a lack of process in terms of setting the agenda and how requests for material were to be circulated became a substantial source of disagreement and contention. We discuss this further in the next chapter.

206. The majority of members agreed that, initially, Scottish Government officials had minimal influence over group meetings, and did not “*guide discussions.*”

*“I would say (they) took more of a role perhaps in terms of supporting the Chair and perhaps rephrasing rather than significantly influencing decisions that were made or processes.”*

207. As the challenges to find agreement became more acute, the role of the Scottish Government officials appeared to change. They started to meet with sub groups within

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<sup>99</sup> See the response at p.31. Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed August 19 2018].

the Group. There was comment of an increasing frequency of meetings between officials from the Scottish Government and both the petitioners and the clinicians.

### **Role of the clinician representatives**

207. The clinician representatives held a number of sub-meetings following the publication of the Interim Report. This was to discuss the structure of Chapter 6 – generally referred to as the “clinicians’ chapter” – and agree on its content. This aim was not met. Disagreement at these meetings was primarily around the presentation of evidence. The primary points of contention appeared to be over issues of clarity of presentation and bias/objectivity of the way in which evidence was presented/omitted. Tensions and discord appeared to escalate over time within the Group. Outcomes from these discussions began to be “*shared*” with some other members of the Mesh Review but not officially to the group as a whole.

209. There was no agreed process or parameters within which these sub meetings took place. There was no agreed mechanism for feedback to the rest of the group. In the absence of any agreed rule of conduct, these sub-meetings deteriorated and differences remained unresolved. There should be a process for sub meetings of a review, addressing how they are conducted, minuted and their discussion fed back to the core group.

**We recommend that group members of a review have equal access to information and points of contact.**

## The petitioners

210. The petitioners gave evidence to the Public Petitions Committee of the Scottish Parliament<sup>100</sup> that they felt physically isolated, at one end of the meeting table, when attending the meetings. During our interviews we asked other members of the Review what their recollection or perception was in this matter.

211. The majority of members strongly disagreed with the petitioners' assertion that they were physically or socially isolated within Mesh Review Group meetings.

*"That's not my recollection of events. They, I remember on all occasions that they were given the opportunity to be together and certainly the Chair made every effort to be as inclusive as possible."*

*"I wouldn't say they were ignored or isolated, that was not my experience."*

Only one member suggested that *"they had their own corner."*

212. With regard to the seating arrangements of the petitioners, many members pointed out that the physical dimensions of the rooms and number of people in attendance would have made distancing from other persons logistically difficult. In addition, some members commented that if the petitioners were seated further away from the rest of the group, it would have been a purely practical decision, to sit near the door in order to facilitate ease of entry and exit from the room.

213. There appeared to be little support for the petitioners' perception that they were physically isolated within the various meeting rooms, although the petitioners clearly felt a level of isolation: *"We were a lone voice."*

214. It may be that their perception of isolation was more to do with how they felt their views were received within the strictures of what became a more technical and clinical

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<sup>100</sup> Public Petitioners Committee Session (Session 5) Official Report , 28 September 2017 p35

review. These feelings may have been exacerbated by the challenges of attending lengthy meetings.

215. Occasionally, the Expert Group would meet in the morning and the Independent Review would meet in the afternoon. Given the petitioners and others were members of both, the intensity and duration of these meetings would not have been without its challenges and could have easily have added to their feelings of isolation.

216. One member commented on the need for greater support for panel members in dealing with controversial decisions. They were unsure, however, how the government could provide support (e.g. with media queries) without being seen as “complicit.”

*“What you can learn from this is you need time before a review process takes place to set out the ground rules rather than necessarily convene a review and then determine during the process what those ground rules are but that’s always easy with the benefit of hindsight. Of course, with the Review having pressure from Parliament to drive forward as quickly as possible and therefore those points of process were never really addressed before the process started.”*

**We recommend that consideration be given to providing members of a review with appropriate training and induction covering matters such as conduct and responsibilities, as well as matters pertaining to confidentiality, information sharing outwith the group and how to manage enquiries from the media.**

## Chapter 7: Management and evaluation of the evidence

217. The requirement to have a methodology in place for the management and evaluation of evidence that is both understood and agreed by the members of any review is fundamental. It is necessary so that there is a shared understanding of what and how evidence is to be evaluated and reviewed. Most methodologies will give consideration on how to assess the number and or quality, the form and the weight or impact that each piece of evidence contains. Different disciplines may interpret evidence in different ways, so it is important to have clarity in approach.

218. Failure to effectively manage evidence in this way may result in a lack of agreement within a review and more widely, doubts over the credibility of its findings.

### The Mesh Review

219. Given the large and diverse number of interests represented by the membership of the Mesh Review, discussions should have taken place on what evidence should be considered and how that evidence should be evaluated. The common dominators which should have provided the framework for the methodology should have been both the remit and the terms of reference.

220. Members of the Mesh Review had mixed recollections on the approach taken towards methodology. Some said that there was no agreement on methodology at the beginning of the process, but it was discussed. Others believed that the remit was the only document on methodology the group was provided with. A few perceived a “*change*” in methodology between the Interim and Final Report.

221. As noted in earlier chapters, there did not appear to be any agreement on what type of review this was. The second chair regarded it “*primarily*” for the “*clinical*”



*community*” but acknowledged that it was a “*mix*”. She recognized that there were broader interests too.

222. Similarly, other members of the Mesh Review saw this as a clinical review. Such a review may measure numbers of successful outcomes or complications from treatments and procedures. Such methodologies are among the most rigorous within the discipline of public health and would be easily recognisable by the clinical representatives and professional organisations.

223. One member saw the approach as “*Purely scientific. Sometimes science and presenting evidence scientists would accept and be able to deal with is not going to answer all the questions.*”

224. This approach would not take cognizance of matters such as the effect of complications and how this impacted upon and affected someone’s life. In other words, the methodology used needed to take account not only of quantitative but also qualitative evidence.

225. This was further complicated by the fact that there was not one methodological style applied throughout either of the Reports. Most of the chapters had different authors. As a result, the Final Report lacked coherence in content, style and emphasis. Some of the chapters were very data intense making reading and understanding them potentially challenging for anyone not familiar with the statistical methodology adopted in other parts of the Report.

*“You had to understand confidence intervals and I don’t know how many people there understood confidence intervals.”*

*“I think if an ordinary member of the public was looking at that stuff I think they would have had even difficulties with terminology.”*

226. Chapter 3- which principally described the personal experiences of patients may have been an attempt to try and remedy the perceived inaccessibility of the scientific data marshalled elsewhere in the Final report. Some members of the Mesh Review recognised this dynamic, commenting that it was a mistake to try and turn Chapter 3 into “*a bit of science*” and that it should have been used instead to illustrate patient experiences. This may have gone some way to portray the impact of experiences of transvaginal mesh implants on the everyday life of a single patient. Another member with a clear understanding of methodological approaches echoed this saying:

*“I felt that there needed to be qualitative information because I felt that this side was not addressed adequately but it is very difficult to argue against randomized controlled trials and to me there was a group of women who were desperate for someone to listen and pay attention to their needs and understand them.”*

227. It was suggested that there needed to be an ethnographic study which would have been much more powerful and scientifically rigorous than having Chapter 3 in the format in which it was presented.<sup>101</sup> Another member of the Review dismissed this suggestion on the basis that it would “*take too long*”. The same member who proposed the ethnography felt that “*the individual who was doing the research was very against qualitative research.*”

228. Such studies can take time but, given the duration of the Review, this probably would have been achievable and may have presented what one member termed as a more “*socially cohesive result.*”

229. Agreement on how to evaluate evidence would also have provided some clarity on what evidence should have been considered and what fell outwith the methodological criteria.

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<sup>101</sup> An ethnographic study is one that comes from ethnographic research, a qualitative method where researchers completely immerse themselves in the lives, culture, or situation they are studying.

230. The chapter authors did not apply research criteria uniformly throughout the Report. Some authors took complete control and ownership of their particular chapter. This can be seen in Chapter 4, for example, where the author, **Dr Rachel Wood** also provided a Plain English version. This was made available on her organisation's website.

231. Otherwise, there appeared to have been a lack of consistency across the Review with regard to what could be included and what fell outwith the methodological criteria.

232. This issue was most apparent in the disagreement over an article in an issue of the journal *Nature* that was not included in the data analysis.<sup>102</sup> The stated reason for its omission was that it did not meet the predefined methodological criteria.

233. Prior to the Interim Report, the question of what materials were to be included rested with the evidence analyst, **Phil Mackie**. A Government official clarified that, *"It hadn't been the practice to circulate the papers that were going to be included in the systematic review to all members."*

234. This may have been workable up to the publication of the Interim Report but following its publication, the process for consideration of evidence seems to have completely broken down. Despite the petitioners repeated attempts to have what they regarded as pertinent materials shared with the whole group, this did not happen, nor was this lack of agreement minuted. Pressure to publish a Final Report combined with the lack of consensus on the clinicians' chapter seemed to close down opportunities to review further materials.

235. In any review the membership is likely to consist of people with a range of skills and experience, some of which may be pertinent to the subject matter of the review. There may however be people coming to the review with little or no experience in the subject matter, or certainly no detailed knowledge of the technical, legal or medical

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<sup>102</sup> This is an international scientific publication. <https://www.nature.com/>.

issues which might arise in a review. It is important therefore in any review that some consideration should be given at the outset to the nature of any written materials being considered by the review group and whether any support is required in understanding some of the more technical aspects which are contained therein.

236. The credibility of any published report requires that, whilst its finding may not always find agreement, the methods by which the review has reached its findings are clearly and consistently applied. We recommend that complex, technical information be presented in a way that can be understood by the range of readership who are likely to have an interest in the subject under review.

**We recommend that a methodology to evaluate evidence should be understood and agreed by all members of a review.**

## Chapter 8: The composition and production of a review report

237. Communicating the findings of a review is the culmination of the work undertaken in the investigation. It should reflect the remit and terms of reference. It should be clear and concise.<sup>103</sup> If the subject matter is technical and jargon has to be used, there should be an accompanying explanation and/or a glossary of terms.

238. Members of a review should be given the opportunity to discuss the structure and content of any publication. This ensures that there is understanding of the direction of the work required to produce the report. It allows the members to be able to make a focused contribution to its content.

239. An awareness of who is going to be reading the report is also essential. Whilst it may have been commissioned by an individual government Minister, the interest in the outcome of a review is likely to be much wider and therefore so will the audience wishing to read it.

240. If the subject matter has generated a large amount of interest, then some consideration should be given to circulating the report in advance to key parties giving them the opportunity to prepare for any subsequent media interest.

241. There are mixed views on who has the responsibility for the publication of the report. Suggestions include that it is a matter for the chair and the commissioning

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<sup>103</sup> Smith M (2008) A practical guide to commissioning and conducting investigations and inquiries. Fieldfisher publications at para. 15. Available from: <https://www.fieldfisher.com/publications/2008/12/-practical-guide-to-commissioning-and-conducting-investigations-and-inquiries> [Accessed June 27 2017].

agencies to assist with printing and distribution.<sup>104</sup> Others believe that it is the decision of whoever commissioned the review.<sup>105</sup> We agree that it may depend on the nature of the review and that either option can apply as long as it is made clear where the responsibility rests.

242. Consideration should also be given as to whether there is merit in producing an interim report. Depending on the subject matter, this may provide an opportunity to make any provisional recommendations, which will allow them to be addressed more quickly than waiting for a future publication.<sup>106</sup> It also allows for an early indication of possible directions and conclusions of a final report to be made available to interested parties beyond just the membership of the review. It may prompt the submissions of additional evidence which may justify inclusion in the final report.<sup>107</sup>

243. Irrespective of who is tasked with the drafting of the report, or individual sections of the report, one person should assume the responsibility of having final editorial control. This will ensure a consistency of writing style making any publication more fluid and readable.

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<sup>104</sup> Sir Cecil Clothier quoted in Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective Inquiries Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] at p.48.

<sup>105</sup> Capsticks, quoted in Department for Constitutional Affairs (2004) Response to Consultation [CP ( R ) 12/04] 28/09/2004 Effective inquiries-Summary of Responses. Available from: <http://webarchive.nationalarchives.gov.uk/+/http://www.dca.gov.uk/consult/inquiries/inquiriesCPR-12-04.pdf> [Accessed November 7 2017] at p.49.

<sup>106</sup> Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.22.

<sup>107</sup> Centre for effective dispute resolution( 2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from: [https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p. 70 [Accessed September 6 2018].

## The Mesh Review

244. There was a lack of consensus as to who were the target audience for the Reports. Some members saw the Reports being written for the Office of the Cabinet Secretary; others saw the Reports as a more technical guide for clinicians. Notwithstanding this uncertainty, the minutes from the meeting of May 2015 note that:

“The narrative in the Report referring to all tables must be concise summarising what we know, what we don’t know and use language appropriate for the intended audience.”<sup>108</sup>

245. A lack of clarity as to how the Reports would be written and by whom was mentioned. One member said that they initially assumed a report would be written by a “*senior civil servant*”. The first chair also assumed that the report would be written by someone else but she quickly realised that ‘*a writer wasn’t available to us*’. It appears that a few members volunteered to write their respective parts of the reports; whereas others were specifically asked. The writing of the reports evolved in a seemingly arbitrary as the Review progressed, rather than following a pre-determined process.

246. There did appear to be a broad understanding that the petitioners would be involved in the creation of Chapter 3, often referred to as the ‘Patients Chapter’. One participant noted that, “*we knew the [petitioners] would have input but did not know what their input would look like.*” This was confirmed by another noting that:

“*the patients also were promised to have their own chapter so they can tell their own story but that was not discussed at the beginning. That just happened.*”

247. As the writing process progressed, one participant mentioned their concerns over a lack of “*proper version control*” of drafts during the drafting of the Final Report. This made it extremely difficult to identify and following changes across several drafts.

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<sup>108</sup> Extract from the Minutes of the Independent Review, (paper no. IR/31) from meeting of May 28 2015.

248. Access to different sections of the report appear to have been segregated, usually with only those directly involved in the chapter getting sight of drafts prior to the last meeting before the publication of the Final Report. Only exceptionally did the draft reports from the subgroups appear to have been shared with the wider group membership.

249. This lack of consistency caused some frustration. One member described not appreciating having their work publicly critiqued when they could not, in turn; influence the work of other subgroups. Another summed it up saying, *“Oh it was awful and there were bits chopped out and put into different places.”*

## Interim and Final Reports

### Interim Report

250. The minutes are completely silent about how the decision to publish an Interim Review was taken and by whom. *“Well, I never knew that there was going to be an Interim and Final Report.”*

251. Members shared a variety of theories with us on why they believed an Interim Report was published. There was conjecture from some members that an Interim Report was issued to provide clarity on how to address the growing number of patients who were still waiting for treatment, with surgeons being unsure how to proceed.

252. The Report was also regarded by some as interim in nature due to the fact that the Group was awaiting the conclusions and publication of what were regarded as two key studies. The first was the final opinion of the European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)<sup>109</sup> on the use of

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<sup>109</sup> Scientific Committee on Emerging and Newly Identified Health Risks (2015) Opinion on The safety of surgical meshes used in urogynecological surgery. European Commission. Available from:



mesh implants which was published on 3 December 2015. The second was the Prolapse Surgery: Pragmatic Evaluation and randomised Controlled Trials, known as the PROSPECT<sup>110</sup> study. This was published In December 2016. Its lead author, **Professor Catherine Glazener** was a member of the Review, so, for some, at least, its findings were already known:

*“You see we knew what was in the PROSPECT study and it needed to be published in an appropriate journal. It was submitted to the New England Journal of Medicine but not accepted. It was then submitted to the Lancet but that process takes so long.”*

253. Finally, a few members alluded to the Interim Report coming about due to political pressure. One participant stated that the impetus to publish the Interim report was due to “*the Minister*” shortly “*appearing before parliament*.”<sup>111</sup>

254. It was clear that the publication of an interim report was not considered at the outset of the review and that the reasons for its publication in 2015 were either not properly discussed with the Review Group or not fully understood by the Group.

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[https://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_049.pdf](https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf) [Accessed September 6 2018].

<sup>110</sup> Glazener C M A, et al (2017) Mesh, graft or standard report for women having primary transvaginal anterior or posterior compartment surgery: two parallel-group, multicentre, randomised controlled trials (PROSPECT) the Lancet 389 10067 at pp389-392.

<sup>111</sup> We looked to see if the Cabinet Secretary was engaged in any particular activity around the time of the publication of the Interim Report. Two are worthy of note. First, on the 23<sup>rd</sup> September 2015, the Cabinet Secretary references that the Interim report will be coming out at the end of the month or October. This was in response to an MSP asking when the interim results were to be released.

<http://www.parliament.scot/parliamentarybusiness/report.aspx?r=10102> A more specific response on the publication date was provided a week later by the cabinet secretary <http://www.parliament.scot/parliamentarybusiness/28877.aspx?SearchType=Advance&ReferenceNumbers=S4W-27810&ResultsPerPage=10> Second, the Cabinet Secretary also had an appearance in front of the Parliamentary Committee on the 6<sup>th</sup> of October, which is maybe what that participant was referencing, rather than say a parliamentary debate.

[http://www.parliament.scot/S4\\_PublicPetitionsCommittee/Meeting%20Papers/20151006\\_Papers.pdf](http://www.parliament.scot/S4_PublicPetitionsCommittee/Meeting%20Papers/20151006_Papers.pdf).

255. Having said that, the Interim Report appeared to have been cautiously welcomed when it was published, it provided an opportunity to consider the conclusions that had been reached to date. We are of the view that it could also have usefully provided an opportunity for greater public engagement which might have been used to inform the conclusions of the Final Report although this does not seem to have been utilised. The petitioners produced a minority report urging that the recommendations made in the Interim Report should be actioned immediately.

256. Early actions to implement recommendations within an interim report can be valuable when these are providing an indication of the probable direction of the Final Report. There should be an awareness that such conclusions have been reached without the benefit of additional information or studies.

“Interim Reports are an under-utilised approach that can help inquiries deliver more rapidly on the key aim of preventing re-occurrence.”<sup>112</sup>

## Final Report

257. The Interim Report could have provided a base from which to progress to a final publication. Some members agreed seeing it as an “*updating exercise*” but others expected wider ranging changes.

258. During our conversations, there were concerns expressed that the Final Report was not very readable in general and that the boxes, which had been added to the start of each chapter, made it even more fragmented. One member questioned this approach but was told that “*this was how updates were done*” and that the boxes would help to draw attention to any updated materials appearing in the Final Report.

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<sup>112</sup> Francis R (2013) Oral Evidence to the House of Lords Select Committee on the Inquiries Act 2005, House of Lords, Q205 cited in Institute for Government((2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.22.

259. One member claimed that there was an increased governmental involvement in the late stages of the publication of the Final Report. They alluded to a lot of issues “*behind the scenes*”, and it “*all getting a bit strange*” and that, consequently, the process overall was becoming disrupted.

*“I didn’t like how the second [Final] report came out. That was the way the Scottish Government did their reports so we were assured that was the best way and I went with that. It was not of a normal or easy reading way and I would certainly never have written it in that way.”*

260. Changes also started to be made to phrasing and terminology which had been used and accepted in the Interim Report. Such changes did not seem to be supported by any rationale nor was there any discussion with the members of the Mesh Review Group. One controversial example was contained within a paragraph in the Interim Report discussing the concerns that some women had expressed to the clinical teams about their treatment, and included the phrase, “*found that they were not believed.*” The Final Report by contrast, subtly but significantly alters the language of this phrase to “*feeling they were not believed.*” The implication in the Interim Report was - that the women patients expressed concerns which were not accepted as medically well-founded. The petitioners’ view was that the Final Report’s shift of emphasis portrayed their concerns as something that they alone imagined.

261. A Scottish Government official suggested that the change was due to stylistic differences in proof reading staff, rather than an active decision. No one was able to recall a discussion over the change for that particular wording.

262. If this change was made simply due to the stylistic preferences of a different proof reader then it serves only to demonstrate the importance of having one person with editorial control. Given the obvious sensitivities of the subject matter, and the experiences of the petitioners in particular, is unfortunate that this particular phrase was

changed without any active consideration behind it. There was no discussion with the petitioners to make them aware of the proposed change or to have an opportunity to comment on it. Whatever the reason, it is clear that this change caused hurt and dismay to the petitioners.

263. More generally concerns over the use of terminologies were raised. The use of Plain English was discussed at the second last meeting to be held prior to the publication of the Final Report, suggesting that plainer English be used where possible.<sup>113</sup>

“Some concerns were raised that there were differences in terminology used depending on the report that was being referred to, and that this made it more difficult to compare the findings from each report.”<sup>114</sup>

264. This resulted in an action for one of the members to “standardise terminology as much as is practicable, and look at the possibility of using plain English.”<sup>115</sup>

265. Unfortunately, this was not followed through. When we enquired why not, we were told “*it was due to the fact that [we] ran out of time.*”

266. As mentioned earlier, a few members commented on having issues with the approach taken in Chapter 3 which was seen as the “*patients’ chapter*”. In particular, some had issue with the chapter being written “*for the petitioners*” rather than for all patient representatives.

267. The majority of those we spoke to were surprised to know that the patient representative, **Isobel Montgomery** who had experienced a good outcome, was not included in the evaluation or narrative in Chapter 3.

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<sup>113</sup> This was held on January 23 2017.

<sup>114</sup> Extract from the Minutes of the Independent Review, (paper no. IR/46) from meeting of January 23 2017.

<sup>115</sup> Extract from the Minutes of the Independent Review, (paper no. IR/09) from meeting of August 25 2014.

*“I’m extremely surprised that the patient’s commentary or reportage would not have been included.”*

268. Mrs Montgomery said that she had to argue for her testimony to be included in the Final Report, where it appeared as an appendix. She wondered why she was not asked to contribute to Chapter 3. She did enquire. She prepared a *“long statement”* and submitted it to Phil Mackie. He reviewed it and said that he would *“extract from it what he thought was useful.”* She believed it all to be useful and informed Mr. Mackie of this.

269. In a Review of this type, a chapter containing a qualitative account of individual patient experiences was relevant and could be valuable. However, it seems to be anomalous that there was a patient representative on the review with a good outcome and yet her testimony was not included in the narrative of chapter 3. We recognise that there were narratives of others who had a good outcome, but these came from individuals outwith the Mesh Review Group. Chapter 3 was instead a representation of experiences from women who were associated with the Scottish Mesh Survivors Group. It provided a powerful narrative, *“voices needed to be represented”* but it should have either been more balanced and included representation from other sources or titled more accurately.

270. Other members alluded to the tensions over the content of Chapter 6; referred to as *“the clinicians’ chapter.”* Concerns were raised between its presentation and form in the Interim Report and how it appeared in the Final Report.

*“I wonder if the [lack of agreement] was a symptom of frustration. I don’t know. I think the trust was gone. I think that once people thought that stuff had been removed and it bore no resemblance to the first one that they had agreed with, it became destabilising and it was just a marriage that had just divorced.”*

271. The petitioners made submissions to the Public Petitions Committee of the Scottish Parliament and to our Review suggesting that evidence had been “lost” or “destroyed” in the Final Report.<sup>116</sup> Their concerns focused on a lack of publication of what they described as “patient friendly” tables, some of which contained “alternative evidence which did not favour mesh.” Only one of the tables was included in the body of the report, with the others “hidden in an Appendix or website amongst obscure data.”<sup>117</sup>

272. We found no evidence to support the claim that evidence was deliberately concealed.

273. Whilst no-one we spoke to accepted that any form of evidence was “lost or destroyed”, several members did accept that moving certain information to the appendix in the Final Report might cause people to believe that it “*decreases its importance*” and made it harder to find.

274. We note that the rationale for including some evidence in Appendices was not fully explained in the Final Report. The second chair intimated to the Public Petitions Committee that certain evidence was presented this way because of a lack of consensus by the clinician members of the review.<sup>118</sup>

275. We are not persuaded by this explanation. In our view this should not have precluded the inclusion of relevant information in the body of the Final Report. Instead any lack of agreement should have been reflected in the body of the Report with an explanation of why this was the case.

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<sup>116</sup> This was a written submission to the Committee on May 8 2017. See also, Public Petitions Committee (2018) PE1517 Polypropylene Mesh Medical Devices, 4<sup>th</sup> report session 5 para 112-116 available from: <https://sp-bpr-en-prod-cdnep.azureedge.net/published/PPC/2018/8/21/PE1517---Polypropylene-Mesh-Medical-Devices/PE1517%20-%20Polypropylene%20Mesh%20Medical%20Devices.pdf> [Accessed September 5 2018].

<sup>117</sup> Public Petitions Committee (Session 5) Official Report 18 May 2017 col,10

<sup>118</sup> Public Petitions Committee (Session 5), Official Report, 18 May 2017, col 10.

276. An appendix should be utilised for supplementary materials that would enhance understanding of what is contained in the main body of a report.<sup>119</sup> Putting information in an appendix or website may infer that it is of lesser importance than including it in the main body of the Report.<sup>120</sup>

277. The petitioners' resignations followed a lack of resolution in relation to the matters described above. They have described the Final report as "diluted." We asked members if they were surprised that the petitioners had resigned.

*"I don't think anything could have been done to have prevented that."*

Others took a different view:

*"A lot of work would have had to be done to get that and there were other pressures then to get it finished. I think that [the petitioners] could have been kept on board but it would have needed somebody else in the Chair and it would have needed different people to be talking to them. Talking in a different way"*

*"At this point there was no sense of let's stop and get them [the petitioners] on board because this is just a document problem, it's a substantive problem of content."*

278. Following the resignation of the petitioners, they requested that their contribution to the Final Report be removed. At a meeting on the 16 March 2017, attended by the petitioners and the then Cabinet Secretary for Health and Sport, Shona Robison, the petitioners asked that "all" of their input from the Final Report be removed.<sup>121</sup> This was

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<sup>119</sup> Nordquist R (2018) Definition of Appendix in a Book or Written Work <https://www.thoughtco.com/what-is-appendix-composition-1689125>.

<sup>120</sup> Gerson S & Gerson S (2000) Technical Writing: Process and Product (3<sup>rd</sup> edition) ISBN- -0-13-020871-X

<sup>121</sup> Public Petitions Committee. PE1517/JJ Petitioners' submission of 8 May 2017. para 10. available from: [https://www.parliament.scot/S5\\_PublicPetitionsCommittee/Submissions%202017/PE1517JJ\\_Petitioner.pdf](https://www.parliament.scot/S5_PublicPetitionsCommittee/Submissions%202017/PE1517JJ_Petitioner.pdf) [Accessed September 12 2018].

to include Chapter 3 and the petitioners' Minority Report. The petitioners were advised that this would be conveyed to the second chair.

279. A series of communications then occurred between the Cabinet Secretary, the second chair and the petitioners.

280. On the 22<sup>nd</sup> March, the Chair wrote to the petitioners by email saying that she understood from the Cabinet Secretary that they wished all their contributions to be removed. She listed what these were and asked them to confirm. They were asked to respond by 10.00 am on Thursday 24 March. Thursday was the 23 March, not the 24. The petitioners indicated that this email caused them distress and that they felt pressured by the deadline given to respond. They confirmed their request, the following day 23 March, to the chair and the Cabinet Secretary.

281. On the day of the publication of the Final Report, the petitioners received a communication from the Cabinet Secretary intimating that it was too late to meet their request. The Final Report was published on March 27 2017. The petitioners' Minority Report had been removed but their input to Chapter 3 was still included in the Final Report.

282. The chair also sent a letter by post which was dated 23<sup>rd</sup>, but posted on the 27<sup>th</sup> and received on the 29<sup>th</sup> March. The letter said that she had not received a response from the petitioners confirming that they wished all materials to be removed.

283. During our discussion with the Chief Medical Officer, **Dr Catherine Calderwood**, she accepted that the petitioners had wanted the Cabinet Secretary to make a request to the chair to remove the materials. Dr Calderwood took the view that the Cabinet Secretary, to maintain Ministerial independence, could not intervene. Instead, she said that the Chair "*needed to make that decision for herself.*" She accepted that this was not the petitioners understanding at the time.



284. These communications took place over a very short space of time. There were 11 days between the petitioners' initial meeting with the Cabinet Secretary and the publication of the Report. The lines of responsibility appeared to be unclear regarding who should have had final say on whether the materials were to be included. The petitioners believed that this had been resolved following the initial meeting on March 16<sup>th</sup> and that their request would be carried out.

285. We question why more time could not have allowed to resolve the matter, or at least to try and reach an understanding in relation to what would be included in the final publication and why this would be the case. Giving evidence to the Public Petitions Committee, the Chair said that the request to remove materials came after the report had been agreed by the remaining members.<sup>122</sup> There are no minutes however, to show if or when this was discussed.

286. If it was not possible to reach an agreement between the remaining members of the Review and the petitioners, then this should have been acknowledged in the body of the Final Report. It should have been noted that such a request had been made by the petitioners but that a decision had been taken that it could not be removed.

287. Whilst differences in writing style and presentation were acknowledged by the first chair in her preface to both the Interim Report and Final Report, we believe that this greatly detracts from the overall cohesion of the Reports.<sup>123</sup> A clear example of this can

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<sup>122</sup> See also, Public Petitions Committee (2018) PE1517 Polypropylene Mesh Medical Devices, 4<sup>th</sup> report session 5 para 112-116 paragraphs 127-128. Available from: <https://sp-bpr-en-prod-cdnep.azureedge.net/published/PPC/2018/8/21/PE1517---Polypropylene-Mesh-Medical-Devices/PE1517%20-%20Polypropylene%20Mesh%20Medical%20Devices.pdf> [Accessed September 14 2018]

<sup>123</sup> The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women Interim Report. (2015) at p. v Available from: <https://www.gov.scot/Resource/0048/00486661.pdf> The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women Final Report. (2015) at p. 2 Available from: <https://www.gov.scot/Resource/0051/00515856.pdf> [Accessed September 12 2018]

be seen when comparing the narrative and style of Chapter 3 in comparison to the intense clinical language and sophisticated presentation of data in Chapter 5.

288. There needed to be a stronger editorial responsibility and control over what and was not included and how it was presented.

289. The lack of editorial control over the content and structure resulted in a piecemeal Report which was ultimately difficult to both read and understand. Throughout both Reports there are issues with clinical language not being defined and a glossary of terms could have helped aid understanding.

290. An additional factor was the perceived increasing urgency to complete the Report. This left a number of matters unresolved. For example, it left a very short time to address and acknowledge in the Final Report that the petitioners had requested that their input be removed and provide reasons why this could not be done.

**We recommend that it is clearly defined who has editorial control for the structure and composition of any report.**

**We recommend that there is a clear understanding of who has responsibility for the printing and publication of any report.**

## Chapter 9: The timeframe, administration and budget of a review

291. Well-drafted terms of reference should set out the proposed timescale for the investigation.<sup>124</sup> The timescale should have regard to the nature and scale of the proposed work to be undertaken. Other factors including administrative support and the availability of the chair and other members of the review will influence the time that the review will require. There is no collated data available in Scotland on timescales for commissioned investigations generally but some post 2000 examples of non- statutory investigations include the following:

- Report of the Scottish Prisons Commission was commissioned in September 2007 and reported in July 2008.<sup>125</sup>
- Independent Review of Transvaginal Mesh Implants was commissioned in June 2014 and reported March 2017.<sup>126</sup>
- National Cremation Investigation was commissioned in June 2014 and reported July 2016.<sup>127</sup>

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<sup>124</sup> Centre for effective dispute resolution (2015) Setting up and running a public Inquiry. Guidance for chairs and commissioning bodies. Available from:

[https://www.cedr.com/docslib/CEDR\\_Setting\\_Up\\_and\\_Running\\_a\\_Public\\_Inquiry\\_-\\_Guidance\\_for\\_Chairs\\_and\\_Commissioning\\_Bodies.pdf](https://www.cedr.com/docslib/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf) at p. 20 [Accessed September 6 2018].

<sup>125</sup> Report of the Scottish Prisons Commission. Chaired by the Rt. Hon. Henry McLeish. Available from: <https://www.webarchive.org.uk/wayback/archive/20170104170934/http://www.gov.scot/Resource/Doc/230180/0062359.pdf> [Accessed September 6 2018].

<sup>126</sup> Independent Review of Transvaginal Mesh Implants. chaired by Dr. Lesley Wilkie (Interim Report) and Dr. Tracey Gillies (Final Report). Available from: <https://www.gov.scot/About/Review/Transvaginal-Mesh-Implants> [Accessed September 8 2018].

<sup>127</sup> National Cremation Investigation. Chaired by the Rt. Hon. Dame Elish Angiolini DBE QC. Available from: <https://www.gov.scot/Resource/0050/00503329.pdf> [Accessed September 6 2018].

- Use of Biometric Data and Technologies was commissioned in June 2017 and reported in March 2018.<sup>128</sup>

292. The Institute for Government (UK) conducted a comparison on different types of formal independent investigation and noted, that of the 60 inquiries that have completed since 1990-2017, non-statutory inquiries took between one to seven years with a median length of one and a half years.<sup>129</sup>

## The Mesh Review

### Was there a process in place to agree the timeframe?

293. There was an expectation, although not minuted, that the Mesh Review would have a duration of somewhere between six to 12 months. Two members said they were explicitly told it was around a six month commitment; others appear to have assumed this to be the case. This seemed to be very optimistic.

294. A Scottish Government official told us that the first chair was advised that the duration of the Review would be about six months. Based on her previous experience, she believed that it was more likely to be nearer a year. One member criticised the lack of a clear timeline for the report. They contrasted this with other review groups they have participated in, commenting that in other groups:

*“we had a timeline right from the beginning. The topic was smaller so it was different. We had an external person reporting. There was a presentation defined in one meeting and then we had another possible two or three face to face*

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<sup>128</sup> Use Biometric Data and Technologies. Chaired by John Scott QC. Available from: <https://www.gov.scot/Resource/0053/00533063.pdf> [Accessed September 6 2018].

<sup>129</sup> Institute for Government (2017) How Public Inquiries can lead to change. Available from: <https://www.instituteforgovernment.org.uk/sites/default/files/publications/Public%20Inquiries%20%28final%29.pdf> [Accessed July 29 2018] p.12.

*meetings and everything else was done by email and agreement of paper reports.”*

295. Some members drew this to the Group’s attention because they were concerned that the length of time would affect the credibility of the Report. There was a sense of weariness, *“the whole thing was dragging on for a very long time.”*

296. No formal indication was given in relation to the duration of the Review. There was an assumption that it would last approximately six months to one year. The duration of the Mesh Review from its inception to the publication of the Final report was two years and nine months.<sup>130</sup> This was a clear underestimation of the time commitment it ultimately required.

**We recommend that there should be a clear and realistic indication of the timeline of a review. This should be included in the terms of reference.**

**We recommend that the commissioning party should provide oversight and support to the chair to manage and review any lapse in timescale.**

## Administration

297. A few members mentioned having issues with administrative support they were receiving with regard to literature for meetings. A few participants noted not being given enough time to digest the content before meetings; this was seen as especially so for lay members of the group.

*“different people assimilate information at different rates, and I know there has been concern from the Patient Groups that there was not enough time to assess information.”*

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<sup>130</sup> This has been based upon when the Review was commissioned (June 2014) until its Final Publication (March 2017).

298. Members had mixed views with regard to their assessment of the secretariat support they were provided. A common theme was that the secretariat appeared to be “*overstretched*” and under pressure. They stated that the Review did not have a dedicated administrative team therefore the secretariat had to provide support whilst also completing “*their day job*”. The impression provided was that this was the underlying reason for the difficulties encountered by most members, rather than there being any competence issue with the individuals involved.

299. One member felt that the provision of administrative support became more fragmented in the latter stage of the Mesh Review. A Scottish Government official conceded this point, acknowledging that the administrators were so short of time that, in the later meetings following the publication of the Interim Report, the administrator tried to write a “*note of the meeting rather than a minute.*”

*“I mean completely I think poorly supported, too much expected of [them] and I did actually write to commend [them] and say thank you for the things that [they] had done because he really did try to be helpful.”*

300. The first chair believed that the nature of the subject matter should have triggered more support than simply relying on the work of just one person.

301. Administrative support was underfunded. It should have been anticipated that the subject matter of the Review and numbers of the membership of the Mesh Review was always going to require a substantial amount of secretarial support. Apart from the roles that one would expect of a secretariat; preparing the agenda and related papers, arranging accommodation, transport etc., as the Review progressed, the secretariat had additional, challenging duties having to manage an increasing public, political and media interest. Secretarial support was also one of a number of duties that the secretariat undertook in addition to other substantive roles within the Scottish Government.

302. Consideration should be given to the merits of having a dedicated administrative support unit whose responsibility would be to provide administrative support for all reviews commissioned. This would bring with it knowledge, experience and consistency of approach. However, we recognise that this would have resource implications and may lack the flexibility or distinctiveness of approach that would more naturally occur from having a different administration in place for each review.

**We recommend that consideration should be given to the creation of a dedicated administrative support unit within the Scottish Government. This unit could be utilised for all commissioned reviews.**

### IT facilities

303. A number of participants had issues with the video/teleconferencing facilities and alluded to them increasing the difficulty of contributing to meetings if not in physical attendance. “[It] makes a difference ... body language ... making sure everybody has their say.” One member described it as “isolating” and that it was hard to hear, making it difficult to resolve points of contention.

304. This represented an acute problem for both of the chairs and was not conducive to ensuring that the large group involved had the opportunity to be heard. Government officials were aware that the quality of IT facilities was not ideal but it was not within the scope of their resources to be able to address this.

### Minutes

305. Meeting minutes are the written or recorded documentation used to inform what was discussed and what happened during a meeting. They document the key ideas or discussion points that led to a decision.<sup>131</sup> They record actions to be taken. They

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<sup>131</sup> Byrkjeflot H, du Gay P, (2012), Bureaucracy: An Idea Whose Time has Come (Again)?, in Thomas Diefenbach, Rune Todnem By (ed.) *Reinventing Hierarchy and Bureaucracy – from the Bureau to Network*

should be understood without reference to other documents.<sup>132</sup> They are important because they provide a written record of what was discussed and agreed.<sup>133</sup> The extent and nature of what is recorded should be agreed with the Chair at the outset of any review.<sup>134</sup> This should also be made clear to the review's members. Minutes should be circulated as promptly as possible after the meeting. It is suggested that this should be no later than one week from the date of the meeting.<sup>135</sup> This allows the minute taker and the recipient to still have a reasonable recollection of what occurred in the meeting and be satisfied that the minutes record an accurate account. The conclusions of a minute should be clear and precise. If this is not the case, then it could lead to questions and differences of interpretation regarding what was discussed.

### **The Mesh Review**

306. We received comments on the consistency and quality of the minutes. There were clear omissions of relevant matters which should have been recorded in the minutes. These included, for example;

- the resignation of the first chair and why she resigned;
- introduction and background of the second chair;
- petitioners' concerns over the content and structure of the Final Report;
- resignation of the petitioners' and why they resigned;

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*Organizations (Research in the Sociology of Organizations, Volume 35)* Emerald Group Publishing Limited, pp.85 - 109

<sup>132</sup> Cabinet Office (2001) A Guide to Minute Taking. Published 2011. Available from: <https://www.gov.uk/government/publications/guide-to-taking-minutes> [Accessed September 12 2018].

<sup>133</sup> Veerman E (2017) What are meeting minutes and why are they important? Available from: <https://gaiku.io/blog/what-are-meeting-minutes/> [Accessed September 12 2018].

<sup>134</sup> Id.

<sup>135</sup> National Centre for Research Methods (2017) Guidance for recording and circulating minutes. Available from: <http://www.restore.ac.uk/mrp/services/ldc/mrp/resources/communication/recording.shtml> [Accessed September 12 2018].



- resignation of Dr Agur and why he resigned.

307. It was difficult to keep track of who was attending meetings and what their role was. For example, **Julia Wilkens** and **Anne Conacher** are both listed as attendees at the first meeting<sup>136</sup> and **June McAdam** at the second meeting<sup>137</sup> but do not appear on the Interim or Final Reports in the list of members. An explanation of why they did not attend other meetings is not minuted. **Professor Catheryn Glazener** intimated that she was stepping down from the Group in a meeting of March 2016 yet her apologies were noted for the subsequent two meetings.<sup>138</sup>

308. Many of the members said that agreement appeared to be reached during the meetings only for follow-up emails to be sent indicating that this was not the case. The second agenda item for meeting seven<sup>139</sup> notes that agreement on the minutes of meetings four and five have still not been reached. There is no indication in subsequent minutes whether this was ever resolved. A member stated they “*often*” received minutes from meetings which had been held six months earlier.

309. Clinician members met as a sub-group in October 2016. They met again in January 2017 and also spoke via teleconference. The second chair of the review also held teleconferences with the petitioners’ and separately with Isobel Montgomery in January 2017. None of these discussions were minuted.

310. A change of style was noted towards the final meetings when there was a change of the person taking minutes. This resulted in the minutes being very brief and more of a note than a minute.

311. Members of the Review appeared to disagree on what format or style the minutes should adopt. Similarly, there was a lack of understanding as to the purpose of

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<sup>136</sup> Monday August 21 2014.

<sup>137</sup> Thursday October 2 2014.

<sup>138</sup> Her apologies are noted meetings of Monday 23 January and Monday March 6 2017.

<sup>139</sup> Monday March 30 2015.

the minutes. The substantive content should only have been challenged if it was wrong, not if there was merely a difference in opinion on its interpretation. Minutes should have been circulated for approval as soon as possible after each meeting. Failures to reach agreement on key matters should have been minuted and their resolution noted.

**We recommend that the ultimate responsibility for the content of the minutes rests with the chair.**

### Processes adopted for archiving materials

312. Archiving is the process of moving materials that are no longer actively used to a separate storage device for retention. They provide evidence as a source of research, historical and public interest<sup>140</sup>. Files and parts of files should be easily located and retrieved.<sup>141</sup> The Scottish Government usually creates a website for each review which will contain files and materials relevant to the review. The style and format of these varies from review to review.

313. It was useful to contrast the Review's webpages with two other investigations that, whilst different in scope, offered models and templates on how this information could be better organised and hosted; namely, the Infant Cremation Commission<sup>142</sup> and

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<sup>140</sup> The National Archives(2016) Available from: <http://www.nationalarchives.gov.uk/documents/archives/archive-principles-and-practice-an-introduction-to-archives-for-non-archivists.pdf> [Accessed September 20 2018]

<sup>141</sup> Data archiving (2016) Available from: <https://searchdatabackup.techtarget.com/definition/data-archiving> [Accessed September 20 2018]

<sup>142</sup> Archived and available from: <http://www.gov.scot/Topics/Health/Policy/BurialsCremation/CremationCommission> [Accessed June 27 2018].

the Motorsport Event Safety Review.<sup>143</sup> Both of these are hosted on the Scottish Government website.

314. The Infant Cremation Commission (ICC), chaired by Lord Bonomy, also dealt with an extremely controversial and emotive issue that affected large numbers of people in Scotland.

315. The ICC's webpages are well-organised. Of note is the ICC's relationship to other, related areas of the Scottish Government website, including, the policy and legislative processes. These are clearly signposted via the left-hand menu on the ICC's webpage, whilst associated weblinks and documentation are accessible via the right-hand menu. The ICC's remit is also included on the opening webpage, which gives context and background to the associated material. The letter written by Lord Bonomy to Michael Matheson (then Minister for Public Health) upon completion of the ICC's Report also acts as a *precis* to the Report itself.

316. Other differences between the ICC and the Mesh Review include:

- Minutes of meetings are included on the ICC webpages, but Agendas are not;
- Email exchanges are not included on the ICC webpages;
- Declarations of Interest are not included on the ICC webpages;
- The link between the National Committee on Infant Cremation (a legacy group to the ICC) and the ICC are clear, and published papers relating to the National Committee on Infant Cremation are held separately.

317. The ICC's webpages provide more context and background, are better organised, are more streamlined (in that less information is presented, but what is

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<sup>143</sup> Archived and available from:  
<https://www.webarchive.org.uk/wayback/archive/20170105091255/http://www.gov.scot/About/Review/motorsport-event-safety-review> [Accessed June 27 2018].

presented is relevant and, crucially, the rationale for its inclusion is clear), and are more easily navigable.

318. The Motorsport Event Safety Review's webpages similarly, are well organised yet are more in keeping with the Mesh Review's webpages than the ICC's (most likely because there is no association with the policy and legislative process).<sup>144</sup> The Motorsport Event Safety Review's pages provide more context and background, are better organised, more streamlined, and more easily navigable.

319. Other differences between the Motorsport Event Safety Review and the Mesh Review include:

- Minutes of meetings are included on the Motorsport Event Safety Review webpages, but Agendas are not;
- Email exchanges are not included on the Motorsport Event Safety Review webpages;
- Declarations of Interest are not included on the Motorsport Event Safety Review webpages;
- Tabled papers are included on the Motorsport Event Safety Review webpages.

### **The Mesh Review**

320. Compared to other Commissions, Inquiries, Reviews and Panels, the Mesh Review provided a surfeit of information in downloadable documents, including Agendas, Minutes of meetings and related documentation. This included email exchanges, Declarations of Members' interests, alternative versions of chapters, and documentation relating to other Reviews of mesh and tapes. However, the provision of the material was unstructured and sporadic and the criteria for inclusion on the Review's webpages were not clear.

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<sup>144</sup><https://www.webarchive.org.uk/wayback/archive/20170105091255/http://www.gov.scot/About/Review/motorsport-event-safety-review>.

321. There were issues and disagreements in regard to which related documentation and information should be provided on the Review's website and this often led to delays.

322. Processes adopted for archiving materials hosted on the Scottish Government website need to be consistent. They should enhance public awareness and understanding of the process by which any reports, outputs or recommendations were produced. It should also be clear *why* documentation is included, and its relevance. Well-organised and complete documentation would also potentially reduce the number of Freedom of Information requests.

323. These were things that were not done but should include;

- Minutes of meetings to be included but agendas not;
- If Agendas and Minutes are included, these should be stored together on a meeting-by-meeting basis;
- email exchanges are not included;
- The context and background to any Commissions/Inquiries/Reviews/Panels should be included;
- A precis of any report should be included;
- A file type should be agreed for downloadable documents.

**We recommend that there should be a template that standardises what is presented at the conclusion of a Review, and how this information is presented.**

## Budget

324. Statutory inquiries have a range of provisions under the 2005 Act which include meeting the expenses of witnesses,<sup>145</sup> and discretionary powers for the commissioning Minister and the chair to control the costs. No similar regulations apply to a non-statutory inquiry. Despite this, there is no clear distinction between the costs for a statutory inquiry and a non-statutory inquiry.<sup>146</sup> Both types are funded by the government and accountable to Parliament for their expenditure. The amounts that are spent on investigations are significant. The National Audit Office recently produced a Report which notes that the UK government has spent more than £200 million on 26 inquiries that have been established and reported since 2005.<sup>147</sup>

325.. In any review, in addition to having a clear understanding of matters such as remit and timescale, it seems only sensible for there to be early and precise discussions as to what type of budget is being set for the completion of the review.

## The Mesh Review

326. There was no agreed budget for the Mesh Review.

327. The first chair of the Mesh Review said that she enquired as to the arrangements for the budget for the review but was simply told that there was no budget: *“I did say isn’t there a budget and I was informed there is no budget.”*

328. One of the members believed there were *“sticking points”* happening in relation to resourcing. They described making suggestions on retrospective work that could have been done to collect qualitative evidence from those who had good surgical

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<sup>145</sup> Section 40 of the Inquiries Act 2005.

<sup>146</sup> Public Administration Select Committee, Government by Inquiry, HC 51-1 2004-05, 2005, p15 cited in House of Commons Briefing Paper, Statutory Commissions of Inquiry: The Inquiries Act 2005 (2018) at p.18.

<sup>147</sup> National Audit Office (2018) Investigation into Government Funded Inquiries. Available from: <https://www.nao.org.uk/wp-content/uploads/2018/05/Investigation-into-government-funded-inquiries.pdf> [Accessed September 10 2018] at p 4.

outcomes; but that the request was rejected. Another said *“it was very much underfunded”* suggesting that the budget could have been used to provide bespoke administrative support. Other members commented on the lack of funding noting that *“it was inadequate and/or wrongly zoned.”*

329. Neither the chairs nor the members received any remuneration for undertaking the work of the Review. No discussion took place as to what resources were available for the Mesh Review, how these were to be allocated and how they could be accessed.

330. The fact that there had been no discussion at the outset of the Mesh Review around important issues such as resources and budget was a major omission which cannot be overstated. Budget and resourcing are an integral matter for any review and should have been discussed by the commissioning party, in this case, the Government Minister, and the Chair. Before a chair or members agree to become members of a review, they should be aware of what arrangements are being made to properly resource the review. The budget should also inform and identify the priorities and work of the review. A failure in this regard carries a number of risks; not least that the review will not be able to achieve its purpose. Perhaps, just as importantly, it risks attracting the criticism that the commissioning party is simply setting up a review or task force to avoid claims of inactivity on a subject matter without any real interest in ensuring the success of the project.

**We recommend that a budget should be identified at the beginning of any discussion on the commission of a review.**

**We recommend that the chair and members should be advised if there is to be remuneration for membership and, if so, agreement should be reached on the terms of any remuneration.**

## Chapter 10: The management of external influences

331. The origins and nature of many reviews are likely to make them the subject of public, media and political attention. Many of those who agree to become members of a review will not be used to encountering such high levels of scrutiny in their lives. In addition, political interest may mean that a review member will have to engage with politicians, or be called to appear before a parliamentary committee to give evidence.

332. The cornerstones of any review are to restore public confidence and to ensure that lessons are learnt which will inform future practice.<sup>148</sup> Public engagement is therefore a positive and useful element of a review since it can provide feedback and benchmark progress. Use of various forms of media is the primary way to impart the progress and outputs of a review. However, media portrayal can spill over into the review member's private life leaving them apprehensive or, worse; become a violation of their own and sometimes their family's privacy.

333. Political interest also relates to the restoration of public confidence. However, such public and political interest may not always be mutually compatible. Independent reviews can sometimes be seen as a cynical mechanism to deflect criticism and controversy.<sup>149</sup>

### The Mesh Review

334. A few members commented on the negative influence of external factors, primarily the media and the Public Petitions Committee of the Scottish Parliament. One noted that the involvement of the Parliamentary Committee made the Review “*different*”.

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<sup>148</sup> Sulitzeanu-Kenan (2007) Scything the grass: agenda setting consequences of appointing public inquiries in the UK. A longitudinal analysis. *Policy and Politics* Vol. 35 4 629-650 at p 630.

<sup>149</sup> Id.



They went on to state that since it was a petition which was concurrently being considered by the Public Petitions Committee it changed the focus from being about evidence to one of *“the politics of the topic.”* They also stated that they assumed there was a certain degree of political pressure being exerted on the process. Others alluded to competing interests; namely the Cabinet Secretary, the Public Petitions Committee and individual political interest, commenting: *“We seemed to have three masters.”*

335. Both chairs and several members of the Mesh Review were called to give evidence to the Public Petitions Committee. For the majority, this was their first time before a Scottish Parliamentary Committee. One member described feeling *“brutalised”* by the way the questions were asked by Committee members. Others felt that the Chair of the Public Petitions Committee did not sufficiently intervene to ensure that those called to give evidence could do so without interruptions from the public gallery.

*“As soon as I got out of the [parliament] building I got quite emotional ... but I can’t really talk about it without getting emotional now.”*

336. Given the origins of the Review in a petition to the Parliamentary Committee, it is unsurprising that the subject matter attracted political and public attention. However, the environment in which members had to give their evidence was neither conducive nor appropriate. Aggressive questioning from some members of the Public Petitions Committee, coupled with a full public gallery who were shouting, clapping and gesturing provided a poor environment for members of the Review to engage. Some members who attended were inexperienced and not prepared for what giving evidence entailed. It is recognised that this was an intense and emotional experience for those in the public gallery, but their right of attendance should not have been used as an opportunity to harangue those being questioned.

337. Many members described intrusive behaviour *via* the media due to their involvement in the Review. They also described the anxiety that such intrusions caused.

The participants recounted examples in which both they and family members (including their children) were approached by members of the media who were making enquiries about the report. This uneasy relationship with the media attention was often exacerbated by a perceived lack of support from the Scottish Government as to how to deal with such queries.

*“We got put out there and we got subject to all this media because I was asked to be part of this Group. I went into this Group to try and sort out working practices in Scotland. I’ve made nothing from it, but I’ve lost a lot. Never again.”*

338. Most members were unprepared to deal with the scale of public and media attention. Some contacted the Scottish Government when approached for comments by the media and some received certain advice whilst others didn’t. Some approached other agencies for assistance.

339. There seemed to be confusion over the Government’s perception of their independence versus providing adequate support to members of the Review:

*“Their argument was that you are independent, if we get involved, you stop being independent.”*

340. The whole process seemed haphazard and inconsistent. Some members were concerned with levels of what they regarded as invasion of their private lives for example, when journalists approached their homes.

341. It is important to recognise the right of journalists to ask critical questions of individuals who have been involved in reviews into matters of public interest. This is a cornerstone of freedom of expression in a liberal democracy. Equally, we recognise the right – and the duty – of MSPs to raise, in parliamentary proceedings, the interests of their constituents. However, the media and parliamentarians have a responsibility to examine and report on the work and findings of independent review groups in the spirit

of fair, reasonable and constructive scrutiny. This does not always appear to have taken place in this case.

### Reflections on having been a member of the Mesh Review

342. It is difficult for us to adequately describe the spectrum of emotions that we encountered from those that we met. The majority of members expressed strong, negative reactions towards their involvement in the Mesh Review. This was a combination of factors revolving around interpersonal conflicts within the group, politicisation of the review process, and treatment by the media. They felt totally unprepared for the levels of public and political scrutiny that they received. Some felt traumatized in the aftermath of the publication of the Final Report.

*“I have to say that afterwards I thought I would be extraordinarily surprised if any of my peers would ever take anything on like this again.”*

*“It was terrible, terrible, terrible.”*

343. This is a long way from the public spirit, and optimism expressed from members when they initially agreed to be part of the Mesh Review.

*“I was probably too keen to be helpful and I should have said no. I mean in a lot of ways, I do wish I had said no. It was a horrendous experience.”*

*“Nobody has gone in with an ultimate motive or agenda. You go into this process hoping you are going to do the best for the patient and come out with a reasonable recommendation, but of course different people will have different opinions of that outcome but in retrospect the individuals need to be protected.”*

344. Many members stated their regret at joining the Mesh Review and indicated that they had no intention of being involved in another governmental review in the future.

Members also suggested that governmental reviews will soon struggle to find expert members to chair and participate in such review processes if their experience was typical of how members involved in such reviews were treated.

*“I suspect anyone who had chaired a Review before would absolutely not do to again! Such a poisoned chalice!”*

345. Another noted that it was the fact that it was made so personal:

*“You were always going to get a backlash to a Report but it’s a backlash to the individual that had not been anticipated.”*

346. Those responsible for commissioning the Review should have given some consideration from the beginning, to the levels of interest that the subject matter of the Review would generate. This should have been discussed with all members of the Review, including the chairs. There was a lack of preparation or understanding over the potential level of scrutiny that the Review would attract.

347. The media interest was arguably made more intense due to questions which arose around the independence of the review process and membership resignations. Had these been addressed and resolved at the time, subsequent media interest may have been diffused or lessened.

348. The success of any review is dependent upon its members. It relies on their goodwill and citizenship to give to their time, usually alongside other commitments. They need to believe they can successfully undertake and complete their role. The comments that we received when members reflected on their experiences were highly concerning. Rather than their membership having enhanced their professional expertise and knowledge, it has left them emotionally traumatized and their confidence eroded. This resulted in many members reluctant or refusing to consider undertaking a similar role again. Everyone we spoke to agreed that there had to be a better way to

commissioning, managing and reporting on an independent review. It is hoped that this report can be the starting process to identifying that better way.

**We recommend that if there is reason to believe that the subject under review will attract media and wider public interest, there should be support and media training for both the chair and members of the review.**

**We recommend that training should be provided and reassurances given to members that advice and support to manage media scrutiny is available.**

## **ANNEX 1**

### **ACKNOWLEDGEMENTS**

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Ms Fiona Drysdale  
Advocate  
Faculty of Advocates

The Very Reverend Dr Graham Forbes  
Chair of Mental Welfare Commission for Scotland  
Chair of OSCR (The Office of the Scottish Charity Regulatory)  
Chair of Court, Napier University  
Chair of Scottish Committee of University Chairs

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## **ANNEX 2**

### **WRITTEN SUBMISSION FROM THE PETITIONERS**

Dear Prof Britton

We regret we are not able to meet with you in person for several reasons but please consider this our contribution to your review.

The process of **‘The Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women’**, in our view, seriously undermined the outcome and cannot be trusted. Initially, the above title did not include the word **‘safety’**, and when we questioned this we were told it was not the remit. We pointed out that ‘safety’ was in fact the prime point and purpose of the review as per the Terms of Reference. At the next meeting the word ‘safety’ was added to the title without any discussion, and as a result we were sceptical about the process and purpose of the review from the beginning.

**Lack of Independence and balance:**

- The four surgeon members of the review group were all proponents of mesh.
- There was no anti-mesh surgeon despite repeated pleas from us to address the balance on at least five occasions between: 2 October 2014 – 21 March 2015. In contrast, patients with a positive and negative experience of mesh were represented.
- Three of the surgeons are under litigation – none of them declared this.
- The suspension of mesh called for by former Cabinet Secretary for Health Alex Neil in July 2014 was not adhered to by the two biggest health boards, Glasgow and Edinburgh, who went ahead and continued to implant hundreds of women. Those two boards have lead clinician group members who have clear links to mesh companies (see below). We believe this was not made clear to Mr Neil who has since commented on the issue.
- We have known patient representative Isobel Montgomery for several years and the style/language used on THIS occasion, her contribution to the Final Report, differs from her normal style/language and, therefore, it is our impression that her contribution may not have been her own personal contribution and, therefore we are drawing conclusions about her independence. In contrast, the anti-mesh chapter by women who have been adversely affected by mesh is real – there is **no** input from experts – it is independent.

### **Conflicts of Interest:**

- It is our opinion that Dr Tracey Gillies, a serving NHS Medical Director who is getting her salary from the same government who instructs her, should never have been appointed as Chair of the so called independent review – this is a conflict. We believe that Dr Gillies came to the review with predetermined opinion that mesh is okay, when she declared that her concern was for two women who contacted her at NHS Forth Valley who were ‘anxiously’ awaiting the recommendations of the review as they are suffering from SUI and/or POP. She told us she felt the need to write to these two women to reassure them that she had only recently joined the review group as she didn't want them thinking she had been involved all along! Dr Gillies has since become an executive on a health board currently facing unprecedented legal claims from mesh injured women. We suspect that in addition to her role as a serving NHS Medical Director, this is another conflict of interest.
- Mr Paul Hilton is a main witness for the NHS Central Legal Office. He was asked to give his general medical and possibly patient specific opinion in the forthcoming civil action for damages brought by an unprecedented number of patients in Scotland, upwards of 420 at the present time. His position on mesh was predetermined and it showed a lack of independence as he had already given his opinion to lawyers and couldn't change it. Mr Hilton did the ‘Ward and Hilton Study’ sponsored by Johnson and Johnson (biggest mesh manufacturer), and this research justified bringing mesh into the UK in the first instance. He has received research funding from two mesh companies from 1998 to 2003 and 2001 to 2003 respectively.
- Dr Karen Guerrero lead urogynaecologist for NHS Glasgow has in recent months organised training programmes for gynaecologists, which are sponsored and subsidised by Boston Scientific, which faces a possible criminal investigation in the US. The firm, which supplies mesh to NHS Glasgow, faces allegations it used counterfeit polypropylene resin from China to manufacture implants, some of which, it is feared, may have reached Scotland. It is one of a number of companies which is reported to have paid out nearly £3 billion in compensation to mesh injured patients in the US. Dr Guerrero also led a study sponsored by American Medical Systems, the second biggest mesh manufacturer and the firm that collapsed after announcing £1.2 billion pay-outs in out-of-court mesh settlements.
- NHS Lothian consultant Voula Granitsiotis has taken part in mesh research trials and received travel grants from firms, including American Medical Systems, the

mesh firm that collapsed after announcing £1.2 billion pay-outs in out-of-court mesh settlements.

- NHS Ayrshire and Arran specialist Dr Wael Agur received travel grants and financial support for workshops from Boston Scientific, Ethicon and CR Bard. Although he declared these and contributed to the review for almost three years, his declaration was not published with the other clinicians in the Final Report.
- Patient representative Isobel Montgomery who was said to have had a positive experience with mesh was invited to participate to bring 'balance' to the group. She was involved in several mesh research trials, for which she received almost £3,000 in fees. She is also listed a 'research grant holder'. Her declaration of interest failed to list this.
- Urogynaecologist Mr Ash Monga, a former Chair of the British Society of Urogynaecology (BSUG) sat on the review to represent clinical society and professional bodies. He received expenses from American Medical Systems for a research project which did not go ahead. He was involved in writing a damning survey, which found that only 27 per cent of surgeons were reporting mesh complications to medical device watchdogs. Despite this shocking evidence, Mr Monga failed to push for a mesh registry or mandatory reporting of adverse events to MHRA, leaving it to patients to lobby Health Secretary Shona Robison.
- Urologist Mr Roland Morley, a former President of the British Association Urological Surgeons (BAUS) and member of both Scottish and UK review group was also involved in the damning survey, which found that only 27 per cent of surgeons were reporting mesh complications to medical device watchdogs. He did not push for either a registry or mandatory reporting to a health watchdog, shamefully leaving it to patients to lobby the Health Secretary.

### **Transparency:**

- Scottish Government's Dr Sara Davies told us there was no new evidence since the Interim Report published in October 2015. We did a literature search and found pertinent Cochrane evidence, which Dr Davies later told us she was actually aware of. We later realised that the Cochrane evidence was the subject of the serious disagreement between surgeons and most likely the reason we were not invited to any meetings and kept in the dark for 10 months. This important evidence was removed and eventually hidden in an appendix in the Final Report. The process of transparency had failed.

- **11 November 2016:** Dear Dr Davies we were surprised to hear that you are unaware of any new evidence to include in Chapter 3 of the Final Report. To our knowledge, there have been 3 relevant and important Cochrane reviews published since the Interim Report, there may even be others we've missed. We thought Dr Mackie and or the clinicians in the group would have kept you informed. Are they **all** unaware of these reviews and potential evidence? If so, this is concerning and only serves to lessen our confidence in the scientific and evidence part of the review. We feel strongly that there is information in these reviews that must be included in the Final Report. We want to see this in a table format like Dr Agur and Dr Mackie did for TVT-O vs Retropubic last year please.
- **30 November 2016:** Dr Davies informed us by email of Dr Gillies's appointment as Chair. She added that a date for the 'final meeting' will be circulated shortly and that the draft Final Report will be sent out two weeks before the meeting. We had not been invited to any meetings for eight months at this point and we were told there was no new evidence as we awaited a date for the 'final meeting'!
- **9 January 2017:** Dear Dr Davies, In addition to the three Cochrane reviews we sent to you on 11 November 2016, can you ask Dr Agur and Dr Mackie to include this latest Cochrane review in our requested table please? This is fairer than someone interpreting the results and is the easiest format for lay people to see at a glance risks v benefits.

**Despite at least five requests two written and three verbal that the Cochrane evidence reviews be put in the same table format as the Interim Report to make the information understandable for patients, we were not sent these tables.**

- **21 February 2017:** Dr Agur circulated his comments regarding the Final Report to the whole review group and it was then we learned that the patient friendly 'tables' we had been requesting since November 2016 were in existence since July 2016 and had been prepared by Dr Agur – no one told us! We soon discovered that tables and alternative evidence that did not favour mesh was hidden in an appendix or website amongst obscure data. There was a complete lack of transparency.
- Failure to contain vital information about the EU reclassification of all surgical mesh to highest risk category Class III by using date discrepancies. The Cabinet Secretary and CMO stated that the EU reclassification took place in the first week of April 2017, a few days after the whitewash mesh report was published, and that is why the report did not mention the reclassification. Our understanding

is the reclassification was approved on 22 February (5 weeks before the report was published) and adopted on 7 March by EU Council. We asked the Chair to include the reclassification on 27 February. The Final Report says; “It is anticipated the new EU Medical Device Regulations will include a change to the classification so all “surgical mesh” devices intended for “long term or permanent use” will be Class III”. The report then goes on to down-play the significance of reclassifying surgical mesh to highest risk category by saying; “From a European perspective the current position is that reclassifying these medical devices would not confer any material difference as they are already in the medium to high risk category as non-active implantable devices.” This new ruling would require mesh manufacturers to prove that their product was safe and not based on equivalence as is currently the case.

**Here is a timeline for the related events:**

- **15 June 2016:** Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. EU Reclassification of all surgical meshes to class III, Annex, Page 338, 4.4., Rule 8: <http://data.consilium.europa.eu/doc/document/ST-9364-2016-REV-2/en/pdf>
- **22 February 2017:** Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. EU Reclassification of all surgical meshes to class III, Annex VIII, Page 12, 5.4, Rule 8: <http://data.consilium.europa.eu/doc/document/ST-10728-2016-INIT/en/pdf>
- **8 March 2017:** Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC - **Adopted by the Council on 7 March 2017. EU Reclassification of all surgical meshes to class III, Annex VIII, Page 12, 5.4, Rule 8:** <http://data.consilium.europa.eu/doc/document/ST-10728-2016-REV-4/EN/pdf>



**Question S5W-08557: Neil Findlay, Lothian, Scottish Labour, Date Lodged: 31/03/2017**

To ask the Scottish Government, further to the statement by the Cabinet Secretary for Health and Sport on 30 March 2017 (Official Report, c. 57), what its response is to concerns that the final mesh report does not make clear that the EU classifies mesh as "high-risk".

**Answered by Shona Robison (28/04/2017):**

The Independent Review's Final Report made clear that, at the time of writing, it was anticipated that the new EU Medical Device Regulations would include a change to the classification of surgical mesh devices intended for long-term or permanent use.

It is now confirmed that the new EU Regulations, subject to their formal adoption, will up-classify surgical meshes to Class III. The new Regulations can be viewed here:

<http://data.consilium.europa.eu/doc/document/ST-10728-2016-REV-4/EN/pdf>.

**Current Status:** Answered by Shona Robison on 28/04/2017

- The link Cabinet Secretary Shona Robison provides in her answer to Neil Findlay MSP above is the same link that we provided, which confirms that the reclassification of all surgical meshes to highest risk Class III was adopted by EU Council on 7 March 2017, and the letter confirming this was dated 8 March, well before the Final Report was published. Dr Gillies confirmed to the Committee that reclassification was 8 March.
- Failure to mention the criminal investigations ongoing against mesh manufacturers in three states in America:  
**24 May 2016:** WASHINGTON AG FILES MAJOR LAWSUIT AGAINST JOHNSON & JOHNSON OVER CONCEALED RISKS OF PELVIC MESH: <http://www.atg.wa.gov/news/news-releases/ag-files-major-lawsuit-against-johnson-johnson-over-concealed-risks-pelvic-mesh>  
**24 May 2016:** CALIFORNIA ATTORNEY GENERAL KAMALA D. HARRIS FILES LAWSUIT AGAINST JOHNSON & JOHNSON FOR DECEPTIVE MARKETING OF SURGICAL MESH PRODUCTS: <https://oag.ca.gov/news/press-releases/attorney-general-kamala-d-harris-files-lawsuit-against-johnson-johnson-deceptive>  
**16 August 2016:** KENTUCKY AG FILES A MAJOR LAWSUIT AGAINST JOHNSON & JOHNSON OVER CONCEALED RISKS OF PELVIC MESH: <https://www.youtube.com/watch?v=ShrmwhsmW90&app=desktop>  
Kentucky:

**Consistency:**

- Despite being fully-informed by the Cabinet Secretary that it was our express will ALL our input must be removed from the report as we did not want our name



associated with such a biased report that we believe exposes women to unnecessary harm, Dr Gillies, ignored us and the Cabinet Secretary and went ahead and published all of our input in the Final Report, removing only our Minority Opinion, which was 'too late' to be included in the Interim Report. She sent us a letter with a mistake in the dates. It is unacceptable that a Chair of a review expects lay-members of the group to respond to a serious email within only 24-48 hours, depending on the way the mistake in the dates is understood. When asked by the Public Petitions Committee, Dr Gillies was inconsistent in her answers as to why she published our input when the Cabinet Secretary asked her not to. In one instance, she appeared to blame the Cabinet Secretary for lack of clear communication but in another instance she appears to shift the responsibility for the decision to publish our input to the members of the review themselves. If the Review Group members decided to include our input against our wish, we would like to see written minutes of the meeting or email evidence please. Such inconsistency is a clear indication of unnecessary miscommunication which resulted in the loss of accuracy in relation to our request for our input to be removed. When asked about this matter, the Cabinet Secretary clearly and consistently shifted the responsibility to the review Chair.

**Here is a timeline of events in relation to this miscommunication:**

- **16 March** – Scottish Mesh Survivors (SMS) ask Cabinet Secretary to remove ALL our input from the Final Report, this was acknowledged and said it would be conveyed to Dr Gillies.
- **22 March 18:22** – Dr Gillies wrote that she understood from the Cabinet Secretary that we wanted our contribution removed. She listed ALL items we had contributed and asked us to confirm AGAIN that we wanted them ALL removed. She asked that we respond by 10:00 on Thursday 24th. Thursday was the 23rd not 24th. This email was unnecessary, harassing, confusing and pressurising. This gave us less than 24 hours (or 48 hours, depending on which date was correct) to respond.
- **23 March 23:57** – We did respond although it felt unnecessary to do so, we again asked Dr Gillies and the Cabinet Secretary to remove ALL our input from the Final Report, including our Minority Opinion from the Interim Report.
- **27 March** – Cabinet Secretary wrote to say we had subsequently asked for 'more' input to be removed and this would not be possible – we were too late. We repeatedly asked that ALL our input from the Final Report be removed. We did NOT want associated with the report and it was NOT in our name. Quite simply

we were used in order that the Final Report could publish without it appearing completely biased.

- **27 March** – SG Final Report published. NONE of our input into this Final Report was removed! The only thing removed was our Minority Opinion from the Interim Report.
- **29 March** – POSTAL LETTER received, dated 23 March BUT the envelope dated 27 March from Dr Gillies writes; “Further to my email to you yesterday, I have not heard from you”. She goes on to say that we had asked only that our Minority Opinion from the Interim Report be removed.
- **18 May** – Dr Gillies told the Petitions Committee that the review group had had a meeting to discuss our request to remove ALL our input before the Final Report published on 27 March. “It is right to listen to requests but, that does not mean I would necessarily accede to those requests.”
- **18 May** – Cabinet Secretary: “I met the Chair on 22 March, I relayed to her ALL the concerns that the women had expressed. She then contacted them to ask about a number of pieces of information and to seek clarification of what should be removed. The women responded on, I think, 23 March with a list of information that they wanted to be removed. It was, ultimately, the chair’s decision on whether to accede to that request. She clearly agreed with some of it: she agreed to remove, for example, the minority report and gave her reasons earlier about why she did not remove the other material.”

**A timeline of email correspondence in relation to this miscommunication can be provided for the Committee**

**Membership:**

- Scottish Government’s Dr Catherine Calderwood did not attend any meetings in Scotland despite being included in group emails. She did however participate in some English group meetings.
- Mr Ash Monga and Mr Roland Morley have disappeared from group emails and were not replaced. That raises questions about the clinical societies not being involved in government decisions about the review and suggests lack of independence.
- MHRA’s Dr Neil McGuire, BSUG’s Mr Ash Monga, BAUS’s Mr Roland Morley, Scottish Government’s Dr Catherine Calderwood and Dr Wael Agur were members of both the Scottish and English mesh reviews. No explanation was

given to patients either side of the border why members could wear two hats and support mesh suspension in Scotland but not in the rest of UK.

### **Funding:**

- The Scottish Government spent less than £4,500, the cost of a business class ticket to attend Tartan Week in New York for the First Minister, it has been said, on a report which completely fails to adequately address the issue due to the flawed process. This would suggest that funding was inadequate and or wrongly zoned in our opinion. There was a lack of communication, and transparency and trust was lost after Dr Wilkie resigned. The review lost its independence, purpose, and lost its way.

In short, instead of mesh injured women being at the heart of the review, we were very much lone voices. Our comments and information we believed were important to the review were either not used, not documented in the minutes or they were dismissed. Meeting minutes were not verbatim and were selective to the point we questioned whether we had actually been at the same meeting! The review process and lack of independent leadership after Dr Lesley Wilkie resigned, took its toll on our health.

The Interim Report says; *“The Independent Review expressed serious concern that some women who had adverse events found they were not believed.”* In the Final Report that changes to; *“The Independent Review expressed serious concern that some women who had adverse events **felt** they were not believed”*. We feel strongly that this compounds the idea that Dr Gillies does **not** believe that we were not believed.

We still have women being told their pain is ‘all in their head’ and being sent for psychiatric treatment. Women are suffering prolonged mesh complications because some doctors are still not knowledgeable enough or because they are simply not believed.

Some surgeons are still assuring patients that they won’t be using mesh - they will be using tape. They don’t tell patients it is a ‘mesh tape’. Some surgeons are still misinforming patients that the mesh they use is not the ‘bad mesh’ that is being negatively reported in the media.

We have women who have lost their jobs, careers, their homes, their husbands and partners. Thousands of women across Scotland could find in 10-15 years they have devastating medical problems due to the mesh implanted inside them, and no way of knowing whether it has been caused by potential counterfeit mesh from China.

We have women who are not being given the incontinence products they need because of the injuries they have suffered. And we have the NHS facing the biggest medical claim in Scottish legal history while the mesh manufacturers who have already paid out \$3billion in the US are likely to walk away leaving the public to pick up the tab.

We strongly believe some of the recommendations of the Final Report are unsafe and expose women to unnecessary harm. All of the above process issues undermined the report and trust was lost. We tried our best but when independence, transparency consistency and trust was lost, our hopes were shattered. We hope your review uncovers the truth and includes our views and experience when it is published.

Yours sincerely

Elaine Holmes and Olive McIlroy  
<http://www.scottishmeshsurvivors.com/>



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